DOCTOR OF PHILOSOPHY

The impact of a single brief intervention versus multiple contact lifestyle intervention on change in body weight and modifiable cardio vascular risk factors in adults who have undertaken cardiovascular risk screening

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The impact of a single brief intervention versus multiple contact lifestyle intervention on change in body weight and modifiable cardio vascular risk factors in adults who have undertaken cardiovascular risk screening

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Statement

I certify that Thesis is the work of Janice Rowland and the author is solely responsible for the contents. The contents of this Thesis have not been submitted for any other higher degree.

Signed ……..

Janice Rowland

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Date 19/02/2017 ……

Summary

Obesity is an increasing cause of poor health in Scotland and contributes to many premature deaths. There are a range of preventable conditions for which causal links with obesity have been suggested including; type 2 diabetes, hypertension, hyperlipideamia (which is a major risk factor for ischemic heart disease), cardiovascular diseases (CVD) and certain cancers. CVD relates strongly to lifestyles, and risk factor modifications have been shown to reduce mortality and morbidity. It has become clear that the major contributors to poor cardiovascular health are related to adverse health behaviours namely excess body weight, diet, physical activity and smoking, and that risk assessment and primary prevention of CVD should remain a priority for the Public Health Agenda.

Participants of the TASCFORCE study screening healthy adults over 40yrs for CVD risk were invited to participate in the HF2 randomised comparison study. All participants received the brief intervention at screening, baseline measurements of body mass index (BMI) and lipids. Participants with BMI ≥25kg/m² were eligible for HF2. Questionnaires were mailed after screening to assess general health, diet and activity. On return of the questionnaires participants were randomised to multiple-contact intervention or follow-up only. For 16-weeks the multiple-contact group received monthly information packs and telephone consultations with lifestyle counsellors to help achieve weight-loss goals. Participants were then re-assessed for changes in weight, cardiovascular risk, diet, activity and general health.

The novel components in the HF2 investigation were; a cohort consisting of a middle aged population having undergone CVD risk screening, a fully powered randomised controlled trial of 16 weeks duration with the primary outcome of change in body weight and secondary outcomes to evaluate change in CVD risk factors, using the telephone as the primary mode of delivery.

Per Protocol data indicated the multiple-contact group lost significantly more weight than the brief single contact group (between group difference 1.1kg, CI 0.1563 – 2.0585, p=0.023), however, when adjusted using imputed data, the ITT data showed weight loss was no longer significant (between group difference 0.9kg, CI-0.1420 – 1.9180, p=0.090).

Although the HF2 intervention was not successful in achieving statistically significant weight loss, there were many positive outcomes. There were significant improvements in anthropometric modifiable risk factors shown in the intervention group notably a reduction in waist circumference, total cholesterol and low density lipoproteins. Both groups were successful in achieving weight loss and significantly improving a number of CVD risk factors, indicating that the HF2 intervention and the brief (usual care) advice were effective at initiating behaviour change.
The study was shown to be acceptable with good participation satisfaction feedback for both intervention and control groups, with 94.5% in the intervention group rating the program as “worthwhile or excellent”. This study demonstrates it is feasible to use the screening setting as an opportunity to recruit participants for a lifestyle intervention.

Abbreviations

Alcohol by volume (ABV)

Alcohol Use Disorders Identification Test (AUDIT)

Bioelectrical impedance analysis (BIA)

Blood pressure (BP)

Body Mass Index (BMI)

Brief Intervention (BI)

British Heart Foundation (BHF)

Cardiovascular Disease (CVD)

Capability, Opportunity Motivation and Behaviour (COM-B Model)

Common Sense Model (CSM) – Behaviour Change Model

Control Group (CG)

Coronary Heart Disease (CHD)

Diastolic blood pressure (BP)

Dietary Approaches to Stop Hypertension (DASH)

Dietary Instrument for Nutritional Education (DINE)

Dual Energy X-ray Absorptiometry (DEXA)

Five a day Community Evaluation Tool (FACET)

Food Standards Agency (FSA)

General Lifestyle Survey (GLS)

Glycated Haemoglobin (HbA1c)

Good Clinical Practice (GCP)

Healthforce (HF)

Healthforce2 (HF2)

Health Related Quality of Life (HRQOL)

High density lipoprotein (HDL)

Intention to treat (ITT)

International Physical Activity Questionnaire (IPAQ)

Intervention Group (IG)

Low density lipoprotein (LDL)

Loss to Follow UP (LTFU)

Mental Component Summary (MCS)

Motivational Interviewing (MI)

Myocardial infarction (MI)

National Institute for Health and Care Excellence (NICE)

Per protocol (PP)

Physical Component Summary (PCS)

Quality of Life (QOL)

Randomised Controlled Trial (RCT)

Scottish Health Survey (SHS)

Scottish Index of Multiple Deprivation (SIMD) - identifies small area concentrations of multiple deprivation across of Scotland

Scottish Intercollegiate Guidelines Network (SIGN)

Self-Regulatory Theory (SRT)

Short Form Health Survey Version 2 (SF12v2)

Stages of Change (SOC)

Systolic blood pressure (SBP)

Tayside Screening for the Prevention of Cardiac events TASCFORCE (TF)

Theory of Planned Behaviour (TPB)

Theory of Reasoned Action (TRA)

Total Cholesterol (TC)

Transtheoretical Model of Behaviour Change (TTM)

Waist circumference (WC)

World Health Organisation (WHO)

1 INTRODUCTION

1.1 Overview of the problem

Cardiovascular Disease (CVD) is the number one cause of death globally. More people are dying annually from CVD than from any other cause (1) and mortality rates are expected to increase to almost 23.6 million by 2030, mainly from heart disease and strokes, which are projected to remain the single leading causes of death (1, 2). CVD is the main cause of premature death before the age of 65 in Europe, accounting for over 680,000 deaths each year (3). Thirty one percent of deaths in men and 26% of deaths in women are from CVD (3). CVD can exist with minimal or no symptoms and can progress rapidly. The first clinical manifestation is often catastrophic; acute myocardial infarction (MI), stroke, or sudden cardiac death (4).

CVD relates strongly to lifestyles, and risk factor modifications have been shown to reduce mortality and morbidity (5). It has become clear that the major contributors to poor cardiovascular health are related to adverse health behaviours namely excess body weight, diet, physical activity and smoking, and that risk assessment and primary prevention of CVD should remain a priority for the Public Health Agenda (3).

1.2 The Scottish perspective

1.2.1 Excess Weight

Scotland has one of the highest levels of obesity in the developed countries, third only to the USA and Mexico (6). The most recent findings from the Scottish Health Survey showed that just under two-thirds (64.3%) of adults (aged 16 and over) had excess weight while over a quarter (27.7%) were obese. In 2014 an increase from

52.4% to 62.2% was shown in the prevalence of adults aged 16-64 that were overweight or obese and the prevalence of obesity showed an increase from 17.2% to 26.5%. The greatest increases occurred between 1995 and 2008 and figures remain broadly stable since then (7), however, extrapolating from trend data in the USA, the Scottish Government has predicted that by 2030 adult obesity in Scotland could reach over 40% which would show an increase of more than 50% from 2008 levels (8).

Obesity is an increasing cause of poor health in Scotland and contributes to many premature deaths. There are a range of preventable conditions for which causal links with obesity have been suggested including type 2 diabetes, hypertension, hyperlipideamia (which is a major risk factor for ischemic heart disease), cardiovascular diseases and certain cancers. Other conditions such as respiratory insufficiency, infertility, sleep apnea, depression and anxiety have also been attributed to obesity, highlighting the necessity for successful interventions to reduce body weight and modify risk factors for these non-communicable diseases.

1.2.2 Diet

Poor diet and nutrition continues to be a major cause of ill-health and premature death in Scotland. Unhealthy eating habits are the second major cause of poor health and chronic disease after smoking (9). An increase in fruit and vegetable intake has been shown to significantly reduce the risk of many chronic diseases (10), whereas, high consumption of red and processed meats and alcohol appears to be linked to colorectal cancer which is now the third most common cancer in both men and women in Scotland (11).

Recent studies have looked at the links between consumption of fruit and

vegetables over a broad range of conditions and concluded that vegetable consumption is more important than fruit consumption in explaining reduced risks of certain types of breast cancer (12), stroke (13) and diabetes (14), while reduced risk of coronary heart disease in women (13), and esophageal and stomach cancers (15) are better explained by levels of fruit consumption, highlighting the need to encourage a balance of fruit and vegetable portions when considering behavior change interventions.

1.2.3 Physical Activity

Regular moderate intensity physical activity, such as walking, cycling, or participating in sports has significant benefits for health and weight control. It can reduce the risk of a range of conditions such as cardiovascular diseases, diabetes, colon and breast cancer, and depression (16). In 2014 The Scottish Health Survey reported that 63% of adults were active at the recommended level (150 minutes of moderate or 75 minutes of vigorous activity per week), similar to the proportions in 2012 (62%) and 2013 (64%) (17).

One in five (22%) adults did fewer than 30 minutes of moderate or 15 minutes of vigorous activity per week and a significantly smaller proportion of women than men met the physical activity guidelines (59% and 68% respectively)(17). The main barriers cited by both men and women to preventing physical activity uptake in 2012/2014 were: poor health (35%), a lack of time (32%), and lack of interest (17%)(17), therefore, weight reduction and behavior interventions need to include a range of behaviour techniques to address motivation, goal setting and individual barriers to changing behaviour.

1.2.4 Alcohol

In Scotland alcohol consumption has long been regarded as socially acceptable. The misuse of alcohol not only brings negative social effects but also the potential for harmful physical effects such as hypertension, liver cirrhosis, some cancers, accidents/trauma, and can result in mental ill-health (18). It is also thought that alcohol is involved in 70% of assaults requiring treatment at A&E (18).

Family and friends are often affected by others alcohol misuse with the potential for violence, neglect and/or abuse (19). In 2014 Alcohol Focus Scotland reported an estimated 1 in 2 people were harmed as a result of someone else's drinking in Scotland (20). Changing individuals' views on excessive alcohol intake can not only lead to a reduction in the negative social effects but also reduce risk for the conditions referred to earlier and contribute to weight reduction.

1.2.5 Smoking

Smoking remains the greatest preventable cause of ill-health and premature death in Scotland. In 2014, 20% of adults (22% of men and 19% of women) aged 16 years and over were cigarette smokers (21). Each year in Scotland there are over 10,000 smoking-related deaths and 128,000 smoking-related admissions to hospitals. Smoking prevalence among adults has declined across the UK in the past 40 years, but continues to remain higher in Scotland than in England and Wales (21). Smoking patterns need to be assessed and targeted for cessation within behaviour change interventions targeting weight loss and CVD risk reduction. This can often present a

challenge as many people are resistant to stop smoking due to the fear of gaining weight, which can be a major psychological hurdle to pass (22).

1.2.6 Conclusions

In 2014 life expectancy in Scotland was reported to be 77.1 years for males and 81.1 years for females, but with considerable variation between areas. Scottish males and females have the lowest life expectancy at birth in the United Kingdom. Males and females can expect to live shorter lives (by 2.3 years and 2.0 years respectively) than in England, where male and female life expectancy is the highest in the UK (23).

Continued efforts through controlling weight, improving diet, increasing physical activity and reducing harmful levels of smoking and alcohol intake are necessary to increase healthy life expectancy and prevent ill health from non-communicable diseases. Despite significant Scottish Government investment in tackling health inequalities since devolution, the gap between rich and poor in Scotland remains persistently wide (24). A report into Health Inequalities in Scotland in 2015 pointed out that Government investment in public health campaigns for example to tackle poor diet, lack of exercise, smoking and alcohol often led to disproportionate uptake that could widen health inequalities rather than narrow them (24). The causes of inequality in health in Scotland are considerable and complex, and out with the scope of this thesis to discuss, however, obesity, diet, physical activity, alcohol and smoking are highlighted in every Scottish Government report concerned reducing the incidence of non-communicable diseases and health inequality, and the reason why it is important to continue to look at behaviour change interventions directed at reducing levels of obesity and improving modifiable lifestyle behaviour outcomes.

1.3 Modifiable Risk Factors- an overview

1.3.1 Excess Weight

In the vast majority of cases, excess weight can be treated by caloric reduction and increasing caloric expenditure. Psychologically, carrying excess weight affects many aspects of a person's life, lack of self-esteem, feelings of isolation, difficulty and embarrassment in some social situations creating a cycle of eating food for comfort and consequent weight gain (25). Physically, increasing weight stresses the body particularly the heart as it becomes more difficult to pump blood around the body with the additional pressure resulting in hypertension (26).

High consumption of dietary saturated fats leads to arteriosclerosis which obstructs blood flow contributing to hypertension, coronary heart disease, strokes and myocardial infarction. Intra-abdominal fat increases waist measurement an important indicator of increasing cardiovascular disease risk which consequently affects blood pressure, blood lipid levels and potentially insulin resistance. Insulin is required to process glucose derived from food, the body's primary fuel. When that process is impaired hyperinsulinaemia will result in diabetes, an important risk factor of cardiovascular disease (27).

Studies have shown that moderate intentional weight loss of around 5% body weight or more in overweight and obese adults with a history of diabetes is associated with lowered all-cause mortality. Intentional weight loss of between 5 kg to 10 kg in obese women with some obesity-related illness is associated with lowered cancer-related mortality and lowered diabetes-related mortality (28).

1.3.2 Diet

Much of Scotland's poor health can be attributed to an unhealthy diet. Diet plays a significant role in either protecting or pre-disposing a person to CVD. Diet is one of the most important factors that can alter cardiovascular risk. A diet high in saturated and trans fats can lead to high levels of serum cholesterol which has a strong correlation with a risk of coronary artery disease, heart attack and death. Eating oil rich fish (high in omega-3 fatty acids), once or twice a week has been associated with a decrease in triglycerides, lower blood pressure, reduced blood clotting, a boost in immunity and improved arthritis symptoms and appears to reduce both the primary and secondary risk of heart disease (29).

Dietary fats are important for several aspects of health and optimal bodily function. They are not only a source of energy and are indispensable for a number of important biological functions including growth and neural development but are involved in vital physiological processes such as carrying fat-soluble vitamins A, D, E and K, supporting their absorption in the intestine (30).

A high sodium intake has been linked to hypertension, a major risk factor of CVD. It has been estimated that a universal reduction in dietary intake of sodium by about 1g a day (3g of salt) would lead to a 50% reduction in the number of people needing treatment for hypertension. The same decrease would lead to a 22% drop in the number of deaths resulting from strokes and a 16% fall in the number of deaths from coronary heart disease (31).

Diets high in fruit and vegetables have a number of bioactive components including polyphenols and glucosinolates which protect against heart disease and stroke. Unrefined grains contain folic acid, B vitamins and fibre, all of which are important protectors against heart disease (32). The protective effects of soluble fibre on cardiometabolic diseases is achieved through multiple mechanisms, reducing blood lipids, improving glucose metabolism, reducing chronic inflammation, controlling blood pressure and regulating body weight (32).

1.3.3 Physical Activity

Adults are more likely to maintain a healthy weight if they have an active lifestyle and are less sedentary. Regular physical activity can reduce the risk of developing CVD, type 2 diabetes, and certain cancers. It also strengthens bone and muscle and improves mental health and the ability to retain necessary function in old age such as climbing stairs, shopping and daily activities such as household chores (33). Physical activity helps to regulate weight and improve the body's use of insulin (34). Being active is beneficial in regulating blood pressure, blood lipid levels, blood glucose levels, blood clotting factors, the health of blood vessels and preventing blood vessel inflammation, all of which are potential indicators of CVD (35). Therefore, regular physical activity is one of the most important components of a healthy lifestyle. Current recommendations from the Scottish Intercollegiate Guidelines Network (SIGN) are for an individual to have at least 150 minutes (2.5 hours) a week of moderate intensity physical activity in bouts of 10 minutes or more (36). In addition, for general health, the Department of Health recommend that the UK physical activity guidelines for adults should include a recommendation to

undertake muscle strengthening activities involving the major muscle groups of the body on two or more days per week (36).

1.3.4 Smoking

Smoking has long been recognised as the biggest single cause of preventable ill-health and premature death in Scotland. There has been considerable success in reducing the smoking rate in recent years but smoking continues to be a major contributor to Scotland's poor health. The Scottish Health Survey 2014 reported since 2003 generally, a continued downward trend in the proportion of adults who smoke has been observed. The survey showed a smoking level of 28% in 2003 with a statistically significant decline between 2012 and 2013 (from 25% to 21%). The level in 2014 sits at 22%, a 6% reduction on 2003 (19).

Smoking is the most preventable cause of cardiovascular morbidity and mortality. It has been associated with a two to fourfold increased risk of coronary heart disease, a higher than 70% excess rate of death from coronary heart disease, and an elevated risk of sudden death (37). These risks are increased when combined with hypertension, elevated lipids, glucose intolerance, and diabetes. The risk of smoking and peripheral arterial disease has also been well documented.

1.3.5 Metabolic Syndrome

There has been an increase over the past two decades in the number of people with metabolic syndrome also known as "Syndrome X" (the insulin resistance syndrome). This increase is associated with the global epidemic of obesity and diabetes with a quarter of the world's adult population reported to have the condition (38). People with metabolic syndrome are twice as likely to die, and three times as likely to suffer

a heart attack or stroke. They also have a five-fold greater risk of developing type 2 diabetes compared with people without the syndrome. Up to 80% of the 200 million people with diabetes globally will die of CVD, which puts metabolic syndrome and diabetes way ahead of HIV/AIDS in morbidity and mortality terms yet is not as well recognized (39).

Metabolic syndrome usually indicates high risk of CVD and developing diabetes. Lifestyle has a strong influence on all the components of metabolic syndrome, therefore, the main emphasis in the management of metabolic syndrome should be in professionally supervised lifestyle changes, particularly efforts to reduce body weight and increase physical activity (40).

The contributing components of metabolic syndrome include a combination of a waist circumference of 102 cm (40 inches) or more (in men) and 88 cm (35 inches) or more (in women), high levels of triglycerides and low levels of high density lipids, hypertension and glucose intolerance (type 2 diabetes, impaired glucose tolerance, or impaired fasting glycaemia) (39).

Lower rates of these conditions are seen in subjects who undertake 120 to 150 minutes a week of at least moderate-intensity aerobic activity, and the more physical activity one undertakes, the lower one's risk (33). Current evidence reviewing modifiable risk factors has shown that rates of cardiovascular and other non-communicable disease mortality and morbidity can be reduced by adhering to recommended guidelines for diet, physical activity, weight and smoking cessation (41).

1.3.6 Socioeconomic Class

There is a strong association between all of the risk factors discussed in the previous sections and socioeconomic classification. Marmot's suggestion that elevated long-term stress levels leading to elevated levels of adrenaline and cortisol in the blood in turn causes an increase in cholesterol levels and other physiological risk factors for diseases such as CVD and some cancers is entirely plausible (42). Long-term activation of the body's stress-response increases susceptibility to these potential diseases and significantly increase morbidity and mortality levels in the lower socioeconomic group (42).

1.4 Individual level Change and Opportunities for Change

Individuals' health behaviours are influenced by intrapersonal, socio-cultural, policy and physical-environmental factors. These variables are likely to interact, and multiple levels of environmental variables, such as living and working conditions, and community characteristics are relevant for understanding and changing these health behaviours (43). It is clear that in order for individuals to engage in behaviour change to improve diet and physical activity all the variables discussed previously which exert an influence on the individual's opportunity to engage in healthy eating and physical activity have to be considered, along with the opportunities in everyday life which can promote these. The recently described COM-B model, a new method for characterising and designing behaviour change interventions considers the important factors required to predict behavior intention and facilitate behaviour change across many societal domains (44).

1.4.1 NICE Guidance for Individual Cardiovascular Disease Prevention.

Guidance from The National Institute for Health and Care Excellence (NICE) Charter 2013 (45), has highlighted primary care as an important setting for the promotion of individual physical activity and dietary change for the individual, and as so has made several recommendations in regards to physical activity shown in Table 1.1. These recommendations will be considered in the in the context of the delivery of diet and physical activity advice given at screening and follow up to HF2 study participants in this investigation, and adopt the principals that all health professionals utilise teachable moments to deliver lifestyle advice.

Table 1.1 Summary of Guidance from The National Institute for Health and Care Excellence (NICE) Charter 2013 (45)

• The recognition of the importance of GPs contribution in the promotion of physical activity and dietary change needs to be combined with the expertise of exercise and behaviour change specialists to offer in-depth and continued support to individuals.
• A systematic approach is needed to integrate the promotion of physical activity into general practice rather than it being seen as an 'add on'.
• The need to encourage primary care staff to work on 'lifestyle' issues such as physical activity as currently other priorities compete for attention.
• A requirement for training of GPs and other professionals to promote physical activity and counseling for other lifestyle risk factors
• The design and content of interventions should be based on behavioural theories.
• Interventions should tailor their options for activity on the needs of their participants and offer a range of moderate physical activities, in particular walking.
• Interventions should contain tailored and targeted programmes to reach inactive individuals and contain regular contact and support with primary care staff.
• Promotion of home-based walking and other moderate-intensity physical activities with a choice of local opportunities to be active (46).

1.5 The Challenge of Change, The Environment/Population level Challenges

1.5.1 Population Dietary Changes

The Foresight Report "Tackling Obesities: Future Choices" reported future implications for the increase in obesity, its causes and the evidence for its determinants and their associated uncertainties (47). Evidence from the report supports the concept of "passive obesity" where wider environmental conditions determine obesity irrespective of the desire to prevent increasing weight (47). Recent decades has seen a change in the way the environment and society influences daily living in the UK. Many people are employed in sedentary occupations and continue to be sedentary at home, car ownership has increased, eating habits have changed, in many cases eating patterns are less structured and "fast foods" low cost, energy dense high fat, salt and sugar foods are widely available and consumed on a regular basis.

1.5.2 Environmental Changes

There are several ways of theorising about the influence of the environment for the purposes of focusing research relating to diet. Black and Macinko summarised the literature on neighbourhood determinants of obesity and described the differences between the micro and the macro environment. The micro level environment includes genetic disposition, social class, cultural traditions, and individual demographics such as income, age, education, gender and ethnicity (48). These often fixed determinants go on to influence the macro environment which encompasses social, historical and political factors, such as public policies, food

availability, marketing influences, group-level social factors and the overarching economic, cultural and legislative influences that have shaped the local environment over time.

Each of these levels potentially exerts a direct and indirect influence on behavioural choices (dietary and physical activity behaviours) and can ultimately impact on weight and weight-related morbidity (48). These environments are inextricably linked making the challenge of designing behaviour change interventions complex in the need to address a multitude of factors on an individual and population level.

The number and complexity of determinates which contribute to the challenge of changing unhealthy dietary behaviour described in this theory is reflected in the complexity of the map produced in the Foresight report and shows the variety of systems at play which contribute to the challenge of changing the culture of overeating and its contribution to the increasing levels of obesity (Figure1.1).

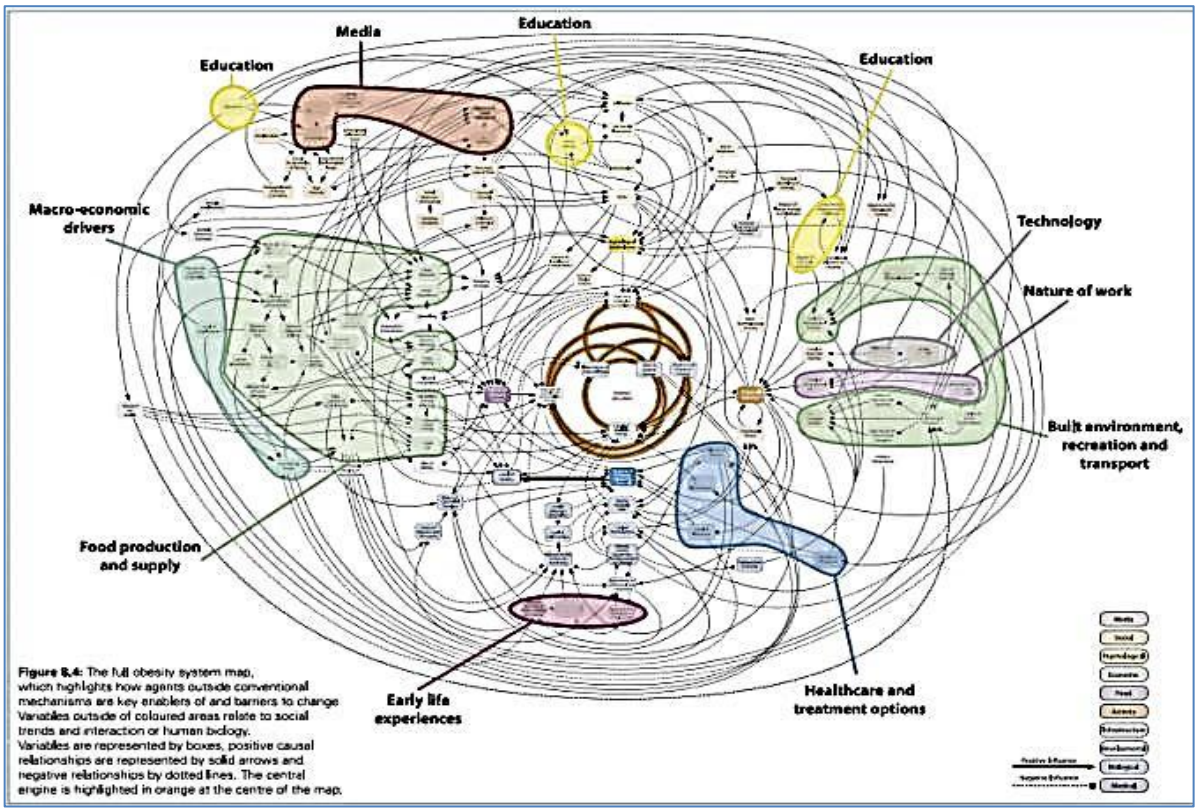

Figure 1.1 Obesity System Influence Diagram: Foresight Tackling Obesity Future Choices Project Report 2nd Edition Government Office for Science. Reproduced with permission.

1.5.3 Physical Activity Changes

Individual behaviour change interventions incorporating educational and motivational techniques to target CVD have been a focus in the past decade with some success. Considering what influences a person's behaviour out with the individual, has triggered considerable thought about the built environment and how it allows opportunities to engage in physical activity. Certain characteristics of the built environment in towns and cities have been related to the prevalence of chronic diseases and mental health (49).

The changes in the way the environment around us have been developed by society and policy over past decades have reduced the need for us to engage in physical activity as part of the daily routine. The demise of an industrial nation, increase in mechanisation and computerisation has reduced the physical side of employment and labour saving devices at home have reduced our household chores. Cars are frequently favoured as a means of transport over walking and cycling all of which has resulted in a decrease in physical activity. The evidence is growing in support for major changes in population levels of physical activity which are required to improve cardiovascular health will require major modifications in environments and social policies.

1.6 TASCFORCE/ Healthforce2

The recently completed TASCFORCE (Tayside Screening for the Prevention of Cardiac events) (TF) investigation was a screening programme designed to identify risk of CVD in apparently healthy adults over the age of 40. Healthforce2 (HF2) is a nested cohort of volunteers within the Tascforce sample.

The HF2 study builds on the previous Healthforce (HF) feasibility study, (also a nested cohort) (50) which demonstrated that it was feasible to recruit 78 (64%) of 121 eligible participants over an eight-month period and successfully deliver an acceptable, three month lifestyle intervention to participants of the TF study (50).

The HF intervention was delivered via three face to face counselling sessions where the goals were to avoid weight gain, increase current levels of physical activity and increase fruit and vegetable intake towards achieving "5 a day". In the intervention group the physical activity goal (to increase moderate physical activity by at least 30 minutes per week) was achieved by 63%, the weight goal (weight maintenance/loss) was achieved by 82%, mean BMI and waist circumference both fell and those reporting regularly eating five portions of fruit and vegetables per day increased (56% at baseline vs. 85% at follow up) (50).

Potential efficacy for the intervention was indicated, but remained to be assessed in a fully powered trial. A review of the literature supported a weight loss specific outcome such as that in the HF intervention had not been tested in a randomised controlled trial of CVD risk screening participants before, however, the relatively high costs inherent in delivering monthly face to face counselling sessions indicated a need for a more cost-effective approach. Healthforce2 (HF2) now aims to assess the outcome of delivering brief (usual care) lifestyle advice versus a more intensive, minimal contact intervention in reducing body weight and modifiable CVD risk factors in healthy volunteers following cardiovascular risk screening.

2. Aim and Objectives

2.1 Aim

The primary aim of the HF2 study was to assess the outcome of a brief lifestyle intervention versus a multiple contact, minimal cost intervention on reducing body weight and modifiable CVD risk factors in healthy volunteers following cardio-vascular risk screening, using the telephone as the mode of delivery.

Primary Outcome Body weight change at 16 weeks

2.2 Objectives

1. To evaluate differences between groups with regard to changes in modifiable risk factors (changes in diet/physical activity, CVD risk and physiological measures).

2. To evaluate change in modifiable risk factors; diet, physical activity, physiological markers of cardio metabolic disease and CVD risk in healthy volunteers following cardiovascular risk screening.

3. To identify the subgroups (eg SIMD, gender) in which this intervention might be more effective.

4. To examine risk perceptions and health beliefs relating to participants CVD risk, and self-reported Quality of Life measures.

5. To assess participant acceptability of a single versus multiple contact intervention approach.

3. Literature Review

3.1 Introduction

The increasing prevalence and acceptance of overweight and obesity in society today has given cause for concern not only for individual health but also on our overburdened healthcare system. CVD, type 2 diabetes and cancers have a direct impact in cost to the NHS in the UK in terms of treatment and long term disability. The importance of implementing effective interventions to address the increasing public health problem has been recognized, but the challenge of changing unhealthy behaviour and implementing successful policy and individual level interventions is yet to be fully realised.

Designing effective behaviour change interventions to reduce the burden of non-communicable diseases and changing modifiable risk factors requires an understanding of behaviour change theory and innovative strategies to enhance participant engagement and adherence. The results of the literature search that was carried out to provide an overview of previous research carried out on behaviour change interventions influencing weight loss are carried out in this chapter.

Some specific areas the search considered related to theoretical behaviour change models and the methodology used to guide weight loss and modifiable risk factors interventions, the behaviour change techniques adopted and how they contributed to positive or negative outcomes, the duration, content and setting of brief interventions, the effectiveness of multiple contacts versus minimal contact face to face interventions and the use of the telephone in behaviour interventions. The search also looked at behaviour change interventions carried out in a screening

setting and primary care as these can be seen as similar settings in the a way that opportunistic lifestyle counselling can be readily applied.

To inform the direction of the HF2 investigation, a breadth of literature was reviewed including empirical research, original quantitative and qualitative studies, systematic reviews and meta-analysis, surveys and government policy and reviews.

3.2 Primary Search

An electronic search was conducted using Cross Search, The University of Dundee federated search service which enables a simultaneous search of up to ten information sources. The Cross Search service allows access to a range of databases; Scopus, Medline, CINAHL plus EBSCO, PsycArticles, Pub Med, and Wiley InterScience Journals (which includes Cochrane) covering disciplines such as Medicine, Dentistry, Nursing, Social Sciences and Psychology.

The "Cinahl Subject Headings List" in EBSCO and MeSH (Medical Subject Headings) equivalent subject heading list in MEDLINE were used to carry out advanced searches and provided an efficient searching tool to choose the most effective terms or subject for the search. In order to identify relevant literature for inclusion in the review the following key words and their combinations were used to carry out the search: Behaviour change, techniques, theory, theoretical models, brief intervention, screening, screening setting, weight reduction, weight loss, telephone, telephone interventions, behaviour change interventions, cardiovascular, CV screening, CVD risk prevention, methodology used in interventions.

The initial literature search was conducted between September 2010 and November 2010 to include literature published between 1990 and 2010. A follow up search was

conducted in August 2011 to October 2011, for literature published between 2010 and 2011. The next search was conducted between September 2012 and December 2012 to include literature published between 2011 and 2012. June 2013 – September 2013 completed the search for the review. A final search was carried out in 2016 for articles published to date.

Boolean operators were used to combine, restrict, widen and exclude specified key words or terms from the results. Reference lists from the selected publications were reviewed and a search for these papers and books was carried out electronically through the internet and e-library to ensure as complete coverage of the literature as possible. Search alerts were set in order to ensure notification of new literature as it was published (Appendix A). Each publication was considered by reviewing the title and abstract and included or excluded from the search as determined by a set criterion (Appendix B).

3.3 Extraction of Data

In order to safeguard validity and rigour in the papers reviewed it was important to seek evidence of the methods used in the collection and analyses of the data, for example aims and objectives of the study, the study population including demographic characteristics, sample size, methods of obtaining the sample, methods of measurement, response and non-response rates, respondent validation, triangulation, evidence of reflexivity on the part of the researcher, acknowledgment of limitations, potential and actual bias in the study, generalisability of the study, main findings and conclusions. In order to minimise bias during the process of extracting data from the papers a check list was used to assess the methodological quality of the studies. The assessment of methodological quality of the studies

included in the review is based on a check list for critical appraisal of studies (51) (Appendix C).

3.4 Secondary Search

In addition to the traditional evidence base a search was conducted manually and electronically via local, national government and public health organisation related websites to reveal "grey literature". Appropriate governmental, Scottish Government, charitable organizations and other authoritative group website documents on strategies to inform public health interventions, manage weight and reduce CVD levels both domestic and international including NICE, WHO and British Heart Foundation were sourced/searched.

These publications are considered worthy of inclusion and bring weight to the evidence presented in this thesis as these policies are informed by research carried out by health practitioners considered expert within their field, and have been used to inform the development of strategies to tackle the prevalence of non-communicable diseases. Using the search terms described in section 3.2 a wide range of empirical literature and systematic reviews were identified and used to influence the direction of this investigation. The next few sections will further discuss the evidence from the literature search into themes integral to the design of the HF2 investigation.

3.5 Findings from Literature Review

The scope for the design of behaviour change interventions is vast, and encompasses a broad range of activities and approaches, which focus on the individual, community, and environmental influences on behaviour. Behaviour

change is more likely to be maintained when a strong motivation has been established or there has been a significant life crisis, when the person making the change experiences a significant benefit reinforcing the ongoing behaviour and when changes are 'sustainable' in that they require little or no ongoing effort or motivation to continue (34).

3.5.1 Interventions for Change – Directions for Best Practice

3.5.1.1 Complex Interventions

Complex interventions can be defined as interventions with several interacting components which can present with an array of distinct problems for evaluators, as well as the practical and methodological challenges which any successful evaluation must overcome (52). Complex interventions are used extensively within the health service in developing social policy and in public health practice. Developing and evaluating complex studies requires a good theoretical understanding of plausible mechanism for intervention to promote change, so that important links in the causal chain can be identified and incorporated into intervention designs.

Three important questions to ask when evaluating complex interventions are what are the active ingredients and how are they exerting their effect, and are these interventions likely to be effective in everyday practice (53). The answers to these questions are necessary to contribute to the growing evidence base for the design and application of effective interventions across groups and settings, and specific to evaluating the key components in previous work carried out in lifestyle behaviour change interventions which can be replicated in the HF2 study design.

3.5.1.2 MRC Framework

In 2000, the MRC published a Framework for the development and evaluation of randomised controlled trails (RCTs) for complex interventions to improve health (54). In 2006 it concluded that, while the initial Framework had been useful, expertise in evaluating complex interventions and a growing interest in the methodology had accumulated since its inception necessitating a review of the 2000 framework (55).

Limitations had been identified in the 2000 framework, and recommendations made to afford greater attention to early phase piloting and development work (56), consideration of a less linear model of evaluation process (57), an integration of process and outcome evaluation (58), and recognition that complex interventions may work best if they are tailored to local contexts rather than completely standardized (59), The key is to be clear about the degree of change or adaptation which is permissible and ensure that variations are recorded in the implementation of the intervention so that fidelity can be assessed in relation to the degree of standardization required by the protocol (52).

In summary the 2006 model advocates that the best available evidence is sourced and most appropriate theory used. Interventions are tested for feasibility to assess whether the study can be done, and piloted, to explore and evaluate the various aspects of the intervention ensuring all the components of the intervention can work together. Surveillance and monitoring of the implementation process should be ongoing, and results disseminated as widely as possible. Evaluation should then be undertaken in order to understand the change process and evaluate effectiveness and cost effectiveness.

3.5.1.3 Context for Change

The way in which a behaviour intervention is delivered can significantly impact on its effectiveness. The context in which it is delivered is important in regard to the setting, the content of the delivery, the personal attributes of the interventionist and the particular personal and social circumstances of the recipient. Significant events or transition points in people's lives may present an important opportunity for intervening in behaviour change interventions (so called "teachable moments") as it is often at these points that people will review their own behaviour.

Typical transition points include being diagnosed or having a family member diagnosed with a serious medical condition, retirement, or bereavement. Behaviour change interventions can be successfully carried out in a range of healthcare settings. Primary care has been identified as a suitable setting in which to deliver behaviour change interventions, principally due to the large number of people using the vast array of primary care services and the frequency with which the services are used (60).

3.5.1.4 *Concept of a Teachable Moment*

Screening a healthy population of volunteers in a research setting for risk of CVD can provide a platform and opportunity to relate individual risk to lifestyle choice and is consistent with the concept of a "teachable moment". The effectiveness of this method of introducing a lifestyle intervention has been shown with the successful weight outcomes from the Healthforce Study where the study sample was recruited from volunteers in a CVD risk screening cohort (50).

Targeting an age group over 40 with this type of intervention may provide the opportunity to target individuals at a time in the life course when they may be more likely to weigh up the benefits of future good health against the burden of ill health and when chronic disease diagnosis is often made amongst friends and family members.

3.5.1.5 CVD Risk perceptions and beliefs

Controlling modifiable risk factors is key to primary prevention of CVD and has been the mainstay of prevention policy in primary care. Individual assessment and discussion of modifiable cardiovascular risk factors is central to prevention strategies as previous work has shown that people are probably less likely to change behaviour on the basis of CVD risk factors they perceive they cannot change (61). Providing feedback and entering discussion with individuals on their biomarker and physiological status may be effective in motivating those individuals to change unhealthy behaviours. A few studies have reviewed risk perception and attitudes on lifestyle change using a variety of formats of risk communication in feedback communications. A prospective, randomised controlled trial by Benner et al, demonstrated patients with hypertension and 10-year absolute risk for CVD of ≥10% receiving education of their risk of MI or death, along with a variety of graphical representation of risk, educating patients about modifiable risk factors and three follow-up telephone calls by a doctor or nurse resulted in behaviour modification and a reduction in CVD risk at 6 months compared to usual care (61),(62).

The study highlights it is possible to combine feedback from individuals biomarker status with other educational material i.e., BMI charts, educational booklets to

convey risk and initiate discussion to make behaviour change. To my knowledge, using risk communication as part of a weight loss intervention has not been tested in a screening setting, although it is recognised that this approach has the potential to change not only weight loss but reduce CVD risk, type 2 diabetes and certain cancers (62).

3.5.1.6 *Brief Interventions*

Research has shown brief advice given in general practice can significantly increase the chances of smoking cessation compared with receiving no advice (63). There is also good evidence indicating the effectiveness of brief interventions in changing eating and physical activity behaviour and reducing body weight, within the primary care setting (64,65). Brief interventions involve opportunistic advice, discussion, negotiation or encouragement and are commonly used in many areas of health promotion by a range of health professionals (66).

A brief intervention is a technique which aims to enable people to think differently or make changes towards positive health behaviour by providing them with the knowledge and skills to change their behaviour. It can be used effectively at any point along the continuum of health promotion, disease prevention, early intervention and treatment, depending on the person's readiness to change, and preferably as early as possible to prevent a problem from developing (67).

They can lead to at least short-term changes in weight loss if they focus on both diet and physical activity, are delivered by practitioners who are trained in motivational interviewing, incorporate behavioural techniques, are tailored to individual

circumstances and encourage the individual or patient to seek support from other people (67).

The content depends on the person, the setting, whether the person is ready to change, and whether it builds on previous interactions.

3.5.1.7 *Brief Interventions in Primary Care*

The evidence reviewed in this section focuses largely on the primary care setting as it most closely resembles the setting and in which the HF2 CVD risk screening will take place and the type of situation where lifestyle modification advice may be given.

Much of the evidence available on this topic has come from studies carried out in the primary care setting, although not exclusively. Interaction with GP's and practice nurses is often instigated by a particular health condition with which the patient has presented such as a chronic medical condition (68). Lifestyle advice given in this context has been shown to be effective showing that patients often retain information if it is directly related to the condition, making it salient and proving more likely to instigate action. The accident and emergency setting has also been shown to be an effective place for brief Interventions to be given particularly in relation to alcohol or drug abuse (69).

Evidence has shown that particularly in a primary care setting GP's are more likely to provide advice to patients at risk of greater health problems especially in chronic conditions or obesity (60). While instigating a brief intervention in this setting is evidently of benefit, it can often be a proven to be a reactive approach rather than pro preventative.

A cross-sectional observational study conducted in eight family medicine practices showed that patient's initiation of a health behaviour topic was four times less likely to result in advice being provided than when a physician initiated the discussion. Advice was more likely to be given if the GP instigated the discussion about the problem rather than the patient (60). These findings suggest variability both in the way patients initiate health behavior discussions and in physician attentiveness or openness to patient initiation of these topics.

This view is correlated by a survey study looking at the characteristics of those patients who were more likely to receive advice; it concluded that patients with a strong patient provider relationship, middle aged adults and patients with chronic conditions were more likely to receive a brief intervention from their GP (70).

Patients initiating a discussion may be more interested and prepared to change, therefore a lack of advice and assistance on the part of the GP could represent a missed opportunity for facilitating health behavior change (71). A cross- sectional survey carried out in the UK supports this view concluding that advice from healthcare professionals increases motivation to lose weight and weight loss behaviour, but only a small number of overweight and obese adults had received such advice. It also highlighted the need for better training for health professionals in delivering brief weight counselling interventions (72).

3.5.1.8 *Barriers to Delivery of Brief Interventions*

A recent study highlighted a variety of barriers which can exist in preventing lifestyle change advice being given, such as perceived time constraints, knowledge, training and confidence (72). Perhaps more importantly healthcare professionals can find

treating overweight or obese patients daunting or even futile, (73) and professionally unrewarding (74, 75, 76, 77, 78).

A questionnaire study with a representative population of primary care providers from four health regions in Scotland investigated primary care providers' views and experiences on providing physical activity advice. The results revealed the same reasons cited in the previous paragraph for staff not providing advice as lack of time, lack of confidence in knowledge of the current recommended levels of physical activity and a feeling of lack of the skills and efficacy needed to motivate patients to change. These factors were highlighted as effecting whether staff would intervene with advice (or not) and the nature of the advice that is given (79). Primary care offers a valuable opportunity for health professionals to discuss lifestyle related issues, however, often GP's and practice nurses are not comfortable discussing these concerns (80).

3.5.1.9 *Future Strategies for Implementing Brief interventions*

In 2016 The Scottish Government released its Local Delivery Plan (LDP) a strategy which proposes more emphasis on person-centred care to support people to develop the knowledge, skills and confidence they need to more effectively manage and make informed decisions about their own health and health care (81). The plan cites primary care as integral to integrated health and social care where the overwhelming majority of healthcare interactions start, and finish both in-hours and out-of-hours. The plan also sets a NHS LDP standard to "Sustain and embed alcohol brief interventions in three priority settings (primary care, A&E, antenatal) and to broaden delivery in the wider setting (81). By supporting the introduction of brief interventions in settings where healthcare professionals can assess individual's

readiness to make health behaviour changes demonstrates a commitment by the Scottish government to challenge healthcare professionals from all disciplines to recognise and engage in utilising teachable moments to encourage the practice to be seen as part of the healthcare professionals role. Through time these skills would then become transferrable to all unhealthy behaviours such as obesity, smoking, diet and exercise.

3.5.1.10 *Conclusion*

It is clear from the evidence that with adequate resources and time afforded to training staff in behaviour techniques such as motivational interviewing, primary care can provide a suitably effective place for initiating behaviour change interventions. This study intended to show the same principles and techniques can be applied to a screening setting to initiate weight loss and show changes in modifiable CVD risk factors using trained nurses and lifestyle counsellors in a cohort of healthy volunteers following cardiovascular risk screening.

3.5.2 Delivery of Weight and Lifestyle Change Interventions

Introduction

This section will outline the merits of individual versus group interventions for delivery of weight and lifestyle change interventions and then explore the different methods of delivery available of communicating and supporting individuals in behaviour change interventions

3.5.2.1 Individual Interventions

It has been recommended that individual sessions should be used for assessment of an individual's readiness to change behaviour (82). They should include behavioural techniques that motivate and support to understand the short, medium and longer-term consequences of their health-related behaviours for themselves and others develop belief in their ability to succeed in a particular situation (self-efficacy) and help make a personal commitment to adopt health-enhancing behaviours by setting and recording goals over a specified time (82).

Advice on how to cope with 'lapses' and 'high-risk' situations and providing ongoing support is also recognised as best practice. For individual or group delivered interventions to be effective in weight loss management interventions requires support in making lifestyle change which can be sustained long term. Both require incorporating behaviour change techniques such as goal setting and self-monitoring and be acceptable to the individuals' personal circumstances with an emphasis on using a well-balanced, healthy eating regular exercise approach.

3.5.2.2 Group Interventions

Group sessions using cognitive-behavioural strategies can be useful to teach skills to modify diet and develop a physical activity programme. They can also provide role modelling and the opportunity for patients to learn from the success of others maximising the benefits of peer support and group problem solving (83).

A one year randomised controlled trial comparing a range of eight management programmes with primary outcome of weight loss at 12 weeks provided evidence that commercial weight management services were more effective and cheaper

than primary care services led by specially trained staff. All of the weight management programs discussed adopted a range of behaviour change techniques with the primary care service using a theoretical component in addition to the behaviour techniques. The behaviour model used was the Stages of Change (section 3.6.3) which, given the different stages an individual can be within the model at any given time may produce bias as to the achievable weight loss within the study timeframe (84).

NICE recommends that primary care organisations and local authorities should only recommend to patients, or consider endorsing, self-help, commercial and community weight management programmes if they follow best practice (85) as shown in Table 2.1.

Table 2:1 National Institute for Health and Clinical Excellence. Obesity: Guidance on the prevention, identification, assessment and management of overweight and obesity in adults. London: NICE; 2006. (85)*Also recommend in SIGN Guidelines (86)

• helping people assess their weight and decide on a realistic target (people should usually aim to lose 5–10% of their original weight)*
• aiming for a maximum weekly weight loss of 0.5–1kg
• focusing on long-term lifestyle changes rather than a short-term, quick-fix approach
• being multi-component, addressing both diet and activity, and offering a variety of approaches
• using a balanced, healthy-eating approach

3.5.2.3 Face to Face

Behaviour change interventions have been traditionally delivered face to face. The major drawback of this mode of delivery is that it is resource intensive and expensive and thus limits the scope for population based cost effective interventions. Lack of time, lack of confidence in current knowledge of guidelines and lack of skills to motivate patients (79), were identified by GP's (section 3.5.1.8) as barriers to engage with patients to change unhealthy behaviour.

3.5.2.4 Text

Studies using mobile technology text messaging as reinforcement in the delivery of interventions are having some success as a means of delivering health interventions. These studies have demonstrated increased adherence to antiretroviral medication in a low-income setting and increase smoking cessation in a high-income setting (87). The "txt2 stop" study, a smoking intervention using text messaging more than doubled biochemically verified smoking cessation (88).

There are now more than 250 smartphone applications that claim to aid smoking cessation, but these have not yet been evaluated adequately (89). Other trials indicated that using text messages to encourage physical activity improved diabetes control but had no effect on body weight (87). Combined diet and physical activity text messaging interventions also have no effect on weight, whereas interventions for asthma control showed suggestive benefits in some but not all cases (87). Whilst there is evidence to support the use of SMS as reminders focused on improving medication adherence and appointment attendance, further evidence of the effectiveness of use over time is required as patients adapt and the effectiveness of the messages diminish as seen in a study by Strandbygaard et al (90).

3.5.2.5 Telephone Interventions

Current literature shows there is solid evidence which supports the efficacy of physical activity and dietary behaviour change interventions in which the telephone is the primary intervention method (91). The evidence for support of this method of delivery was favourable in a combination of telephone and print or face to face sessions being more successful than telephone interventions alone which are rare (92).

Eakin and colleagues reviewed the evidence in a systematic review and highlighted the need for more research using the telephone as the primary method of intervention in studies targeting outcomes in both physical activity and dietary interventions. Only four (93, 94, 95, 96) of the 26 studies under review had targeted both behaviours and only one of those studies recruited healthy adults rather than those with chronic conditions. In this one study the participation rate was not described and there was no theoretical component.

Telephone interventions can offer the capacity to not only provide participants with an opportunity to obtain health related advice from a health professional it can also provide emotional support (97). A meta-analysis reviewing telehealth interventions in secondary prevention of coronary heart disease has also shown that telephone based interventions also were more effective than internet and videoconferencing communication in reducing patients systolic blood pressure and improving lipid profiles (98). This finding is consistent with a study carried out in patients with heart failure where phone interventions improve adherence to medical therapy and reduced hospital admissions (99). Recent evidence from the BeWEL study has shown

intervention participants continued to lose weight over a month period through telephone call interventions only (100).

3.5.2.6 *Conclusions*

In summary there is good evidence to demonstrate that the telephone can still be a valuable means of communicating and supporting individuals in behaviour change interventions as it is readily accessible, and can offer immediate means of personal support, however, there remains a need to have back up with written or face to face consultation. There may also be limitations; for example the inability to measure weight objectively and the potential to miss report self-reported behaviour. There also remains a lack of fully powered randomised controlled trials investigating weight loss interventions where the telephone is the primary method of delivery.

3.5.3 Single or multiple contact Interventions

When designing behaviour change interventions one needs to consider whether to have single or multiple contact, how many sessions are offered, the duration of these sessions and the frequency of follow-up sessions after the initial brief intervention. As well as the format of delivery, consideration also needs to be given to the optimal frequency of contact and duration of each session.

Although there is review level evidence that motivational interviewing (section 3.7.1), can be effective even in brief encounters of only 15 minutes it is clear that more than one encounter with a patient and increased exposure time increases the likelihood of a positive effect (101). In most studies, more frequent and/or longer

contact sessions are associated with greater reductions in body mass and improvements in physical activity and diet (101,102,103).

Reviews have found the median duration of an individual counselling encounter in healthcare settings to be 60 minutes (range = 10–120 minutes) with 64% of the brief interventions (less than 20 minutes duration) showing an effect (104). The interventions with significant benefit beyond 12 months were all high-intensity counselling interventions with group, phone, or mail contact throughout. Most "high-intensity interventions" (promote weight loss through decreased caloric intake and increased physical activity) that had follow-up beyond 12 months showed persistent beneficial changes in adiposity and lipids, as well as improvements in self-reported behavioural outcomes 103).

It is, therefore, recommended that interventions allow sufficient time for consultations, plan to provide repeat consultations and arrange frequent follow-up appointments (104). NICE recommends that for behaviour change to be sustained at one year, several follow-up sessions over a period of three to six months are required after the initial consultation episode (85). Overall, the level of support offered should be determined by the person's needs, and be responsive to changes over time (105).

3.5.4 Current Guidelines: Weight Loss Education/Physical Activity

Two of the key risk factors contributing to non-communicable diseases are diet and physical activity. Diet and physical activity influence health both together and separately. Although the effects of diet and physical activity on health often interact, particularly in relation to obesity, there are additional health benefits to be gained

from physical activity that are independent of nutrition and diet, and there are significant nutritional risks that are unrelated to obesity (106). The national guidelines set out in Tables 3.1 and 3.2 highlight the recommendations on dietary advice and level of physical activity to be used when imparting lifestyle advice. These guidelines have been followed when giving such advice to participants in the HF2 study.

3.5.4.1 Dietary Advice Recommendations

Specific recommendations have been made by NICE for individuals seeking advice on making dietary changes. The specific weight loss advice to be given is set out in Table 3.1. The long term advice to be given should encourage moves toward eating a balanced diet, consistent with other healthy eating advice (107). The recently updated Nice guideline CG 181 provided recommendations to help healthcare professionals identify people who are at risk of CVD including people with type1, type2 diabetes and chronic kidney disease, it offers recommendations for giving advice on recommended levels of physical activity and the components of a cardio protective diet (108).

Table 3:1 NICE Pathways Dietary Interventions and Advice for Adults (2013) (107)

• Dietary changes should be individualised, tailored to food preferences and allow for flexible approaches to reducing calorie intake.
• Unduly restrictive and nutritionally unbalanced diets should not be used, because they are ineffective in the long term and can be harmful.
• People should be encouraged to improve their diet even if they do not lose weight, because there can be other health benefits.
• The main requirement of a dietary approach to weight loss is that total energy intake should be less than energy expenditure.
• Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal less than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss
• Low-calorie diets (1000–1600 kcal/day) may also be considered, but are less likely to be nutritionally complete.
• Very-low-calorie diets (less than 1000 kcal/day) may be used for a maximum of 12 weeks continuously, or intermittently with a low calorie diet (for example for 2–4 days a week), by people who are obese and have reached a plateau in weight loss.
• Any diet of less than 600 kcal/day should be used only under clinical supervision.

3.5.4.2 Physical Activity Recommendations

Physical activity includes everyday activities such as walking and cycling to get from A to B, work related activity, housework, DIY and gardening. It also includes recreational activities such as working out in a gym, dancing or playing active games, as well as organized and competitive sport (109). The National physical activity recommendations given by the Chief Medical Officers (CMO) shown in Table 3.2 state that:

Table 3.2 Start Active Stay Active: a report on physical activities from the four home countries' Chief Medical Officers (2011). (109)

• All adults aged 19 years and over should aim to be active daily.
• Over a week, this should add up to at least 150 minutes (2.5 hours) of moderate intensity[1] physical activity in bouts of 10 minutes or more.
• Alternatively, comparable benefits can be achieved through 75 minutes of vigorous intensity activity spread across the week or combinations of moderate and vigorous intensity[2] activity.
• All adults should also undertake physical activity to improve muscle strength on at least 2 days a week.
• They should minimise the amount of time spent being sedentary (sitting) for extended periods.
• Older adults (65 years and over) who are at risk of falls should incorporate physical activity to improve balance and coordination on at least 2 days a week.
• Individual physical and mental capabilities should be considered when interpreting the guidelines, but the key issue is that some activity is better than no activity (109)

[1] Moderate-intensity physical activity leads to faster breathing, increased heart rate and feeling warmer. Moderate-intensity physical activity could include walking at 3-4 mph, and household tasks such as vacuum cleaning or mowing the lawn.

[2] Vigorous-intensity physical activity leads to very hard breathing, shortness of breath, rapid heartbeat and should leave a person unable to maintain a conversation comfortably. Vigorous-intensity activity could include running at 6-8 mph, cycling at 12-14 mph or swimming slow crawl (50 yards per minute).

3.6 Behaviour Change Theory

Theories are used to describe psychological determinates or predictors of health behaviour, and models have been developed to include wider social determinates such as personal beliefs, environment, and the wider community. Constructing theories about these determinates enables us to test these theories by evaluating interventions targeting these core predictors. In this way theory based interventions can allow us to understand what works and what doesn't and provide the base to build better interventions.

Theoretical frameworks are important in guiding the development of interventions to increase confidence and motivation to achieve successful behaviour change. By omitting to describe any theoretical component in the development of an intervention means the impact of the intervention cannot be tested against any theoretical paradigm.

3.6.1 *Reporting Theory in Behaviour Change Interventions*

The evidence regarding reporting of the application of Theoretical frameworks in behaviour change intervention studies is mixed (110). A review conducted between 2000 - 2005 concluded that approximately one third of the papers reviewed stated a theoretical basis to their intervention but only a small proportion rigorously applied it. Surprisingly, a more recent review in 2010 of systematic reviews on the effectiveness of interventions to change six health behaviours (111) didn't report any meaningful theoretical input into the design of any of the 103 study interventions reviewed.

One limitation of this type of review is that the data included was not primary data and some or all of the theoretical component may not have been reported, however, if making a case for supporting successful interventions and making recommendations for future policy it is surprising that a comprehensive review of the theories used was not reported given the significance of behaviour change theory.

A recent review of communication-related behaviour change techniques used in lifestyle interventions in primary care highlighted a little over half of the 26 studies looked at in the review describes theory as a basis for the intervention and 16 described their theoretical foundation. The report concluded that these interventions were theory inspired rather than theory based and there were very little aspects of the theory linked to the intervention (112), which can be as a result of the difficulty of applying theory in the design of an intervention.

Some of the common models cited in studies identify what predictors of behaviour should be targeted, but not how to go about actually applying the theory to the intervention. Ajzen writes on his Theory of Planned Behaviour "Once it has been decided which beliefs the intervention will attempt to change, an effective intervention method must be developed. This is where the investigator's experience and creativity comes into play" (113). This quote highlights the complexity of behaviour change intervention design, and the need for innovative thinking in the design and implementation of interventions. More recent models have tried to address the issue of the complexity of applying theory in real life in the design of interventions and will be discussed in section 3.6.7.

3.6.2 Models in Use

There are several behaviour change models and frameworks currently in use to guide behaviour change interventions, some of which are described in this section. Most behaviour change interventions, use constructs from established health behaviour change models such as the Trans-theoretical Model of Change (114) the Health Belief Model (115) or Social Cognitive Theory (116). Following review of the literature this investigation plans to use two theoretical models to guide the intervention.

3.6.3 Transtheoretical Model of Behaviour Change

The first The Transtheoretical Model of Behaviour Change (TTM) was originally developed by Prochaska and Di Clemente (1982) and is commonly known as The Stages of Change Model (SOC) (117). The model emphasises the dynamic nature of beliefs, time, and costs and benefits and how they interact over five stages of change (Table 3.3).

Table3:3 Prochaska JO, Di Clemente CC. (1982). Transtheoretical therapy: toward a more integrative model of change. Psychotherapy. 19: p: 276-88. (102)

5 Stages of Change
• Precontemplation: not intending to make any changes
• Contemplation: considering a change
• Preparation: making small changes
• Action: actively engaging in a new behaviour
• Maintenance: sustaining change over time

These stages, however, do not always occur in a linear fashion a person may move to the preparation stage and then back to the contemplation stage several times before progressing to the action stage. Furthermore, even when the individual has reached the maintenance stage they may slip back to the contemplation stage over time. The model examines how the individual weighs up the costs and benefits of a particular behaviour. In particular its authors argue that individuals at different stages of change will differently focus on either the costs of behaviour e.g. stopping smoking will make me anxious in company, or the benefits, stopping smoking will improve my health. A smoker at the action and the maintenance stages tend to focus on the favourable and positive features of their behaviour whereas the smokers in the pre contemplative stage tend to focus on the negative features of the behaviour.

The stage of change model is used both in research and as a basis to develop interventions that are tailored to the particular stage of the individual concerned. The model has been criticized for being too simplistic particularly in its application to complex behaviours such as physical activity and dietary intake (118). Staging models are based on self-assessment, and a person's view on their particular stage in the algorithm is entirely subjective. A person can believe they are taking the recommended amount of physical activity and eating the recommended amount of fruit and vegetables when they are not, they are in fact pre-contemplators where they believe they are in maintenance and in being so are not motivated to change (118).

Most studies based on the stages of change model use cross-sectional designs to examine differences between different people at different stages of change. These

designs do not allow conclusions to be drawn about the role of different causal factors at the different stages ie (people at the preparation stage are driven forward by different factors than those at the contemplation stage). More experimental and longitudinal studies are needed for any conclusions about causality to be valid. The key finding of a Cochrane Review highlighted that the TTM showed limited impact on weight loss and that the weight loss that occurred was not shown to be sustainable. However, the TTM did show that with a combination of physical activity, diet and other interventions (such as feedback and counselling) produced significant effects on other outcome measures, such as change in physical activity, dietary intake and progression through the stages of change process (119). This investigation will use the TTM to inform the HF2 intervention in a randomized comparison study, which has rarely been tested.

3.6.4 The Theory of Reasoned Action

The second model to be used in the HF2 investigation The Theory of Reasoned Action (TRA) (120,121,122) was developed by Ajzen & Fishbein to examine predictors of behaviours and was central to the debate within social psychology regarding the relationship between attitudes and behaviour. The Theory of Planned Behaviour (TPB) model (123,124,125) was a progression from the TRA model and emphasised the belief that the behavioural intention was the outcome of a combination of several beliefs (Figure 3.1). The theory proposes that the behavioural intention should be viewed as “Plans of Action” in pursuit of behavioural goals (126).

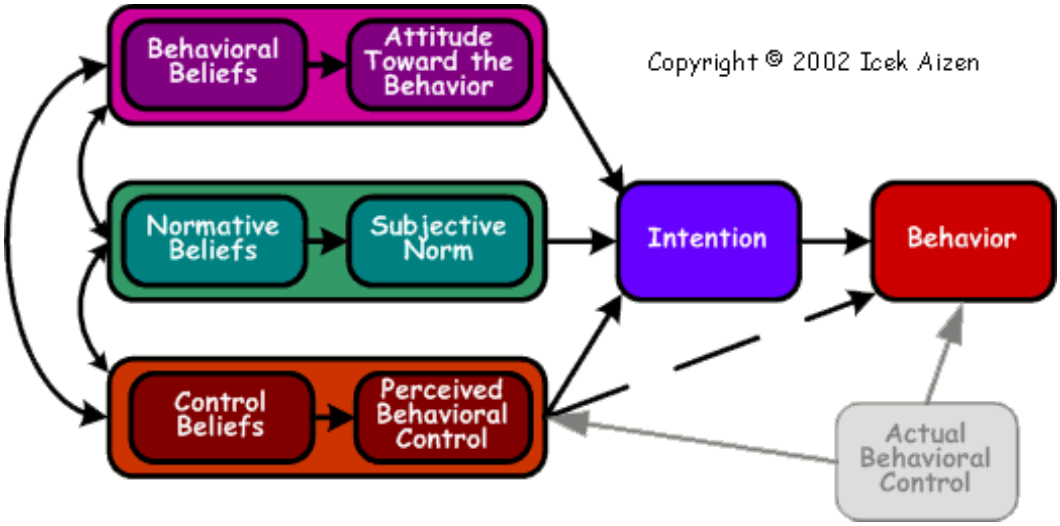

Figure 3.1. Source: Ajzen, I. (1991). The theory of planned behaviour. Organizational Behavior and Human Decision Processes, 50, p. 179-211.

Within the TRA model behaviour change is seen as a function of;

- Beliefs about the consequences or outcomes of the behaviour
- Evaluations of the importance of the outcomes of the behaviour
- The expectations of significant others
- A motivation to conform

The TRA model suggests that people's perceptions of the attitudes of others towards their behaviour could be a powerful influence on them to change. The motivation to comply with perceived social pressure from significant others could cause an individual to behave in a way that these groups/others would think is right. Peer group pressure can be very powerful if the individual values membership of the group or wants to belong to it.

According to this theory behaviour is dependent on the two variables of Attitudes and Subjective Norms.

Attitudes – resulting from beliefs about the consequences of the behaviour and an appraisal of the positive and negative aspects of making a change.

Subjective Norms – What significant others think, do and expect and the extent to which the person wants to conform and be liked by others. Combing the two influences will predict Behaviour Intention.

Ajzen (127) developed the Theory of Reasoned Action in 1991 to include a third variable of control, suggesting people's behaviour is also a consequence of their perceived control, described as Internal Locus of Control, which represents the extent to which a person believes they are responsible for their own health. External Locus of Control represents the belief that an individual's actions are limited by powerful others, chance fate or luck. The inclusion of this element of control was developed by Ajzen into the Theory of Planned Behaviour Model (127).

Locus of control is also described as being linked to socioeconomic status. Self-efficacy is important for individuals in making behaviour choices. Self-efficacy is determined to a large extent by self-esteem which is affected by social economic factors such as education and cultural-social environment.

3.6.5 Self-Regulatory Theory (Common Sense Model)

Risk perceptions are formed through the appraisal of experiences in a person's life. Perceptions can be important motivators to actions such as risk-reduction behaviours. The Common Sense Model (CSM) is a self-regulation model of health

threat, cognition and behaviour which was developed by Howard Leventhal and colleagues and suggests a number of important cognitive and affective aspects of risk perceptions (128,129,130).

The CSM explains that individuals appraise their beliefs and knowledge about an illness to form their view of that illness. People's perception of health risk is based on perceptions of a particular illness or disability, and creates the development of a representation of illness risk. Understanding risk perception, therefore, must include a theoretical understanding of illness representations. The risk perception is then realized when the discussion around the 10 year CVD risk and other measures; BMI and blood pressure are discussed. This in turn will allow us to see if the communication of CVD risk has predicted behaviour change in the brief intervention and the HF2 intervention groups.

People may show consistent beliefs about illness that can be used to make sense of their illness and help their understanding of any developing symptoms. These illness cognitions have been incorporated into a model of illness behaviour to examine the relationship between a person's cognitive representation of perceived illness and their subsequent coping behaviour. This model is known as the "Self-Regulatory Model of illness behaviour" (131).

One issue to consider is whether measures of risk judgments and worry are sufficient indicants of the illness representation attributes influencing behaviour, or whether we need more detailed assessments of the illness representations in order to predict responses. It may be that influences of representational beliefs on

behavior are completely accounted for by simple measures of risk judgment and worry (132).

3.6.6 What are Illness Cognitions?

Leventhal, Meyer and his colleagues (131) defined illness cognitions as "a patient's own implicit common sense beliefs about their illness". They propose that these cognitions provide patients with a framework or schema for coping with and understanding their illness, and telling them what to look out for if they are becoming ill. Using interviews with patients suffering from a variety of different illnesses, Leventhal identified five cognitive dimensions of these beliefs shown in Table 3.4.

Table 3:4 Leventhal's five cognitive dimensions of beliefs

• Identity, (the label or diagnosis)
• Perceived cause of the illness (biological or psychological),
• Time line, (how long the illness will last)
• The consequences (possible effects illness will have on their lives)
• Curability and controllability (believe that the illness can be treated and cured and the extent to which the outcome for the illness is controllable either by themselves or by others).

This model is based on approaches to problem solving and assumes that given a problem or a change in the status quo the individual will be motivated to solve the problem and re-establish their state of normality.

Once the individual has received information about the possibility of illness according to problem solving theory the individual is then motivated to return to a state of "problem-free" normality. This involves assigning meaning to the problem, the first stage in a process. According to Leventhal the problem can be given meaning by accessing the individual's illness cognitions. Therefore, the symptoms and social messages will contribute to towards the development of illness cognition, which will be constructed according to the following dimensions; identity, cause, consequences, timeline cure/control. These cognitive representations of the "problem" will give the problem meaning and will enable the individual to develop and consider suitable coping strategies (131).

However, a cognitive representation is not the only consequence of symptom perception and social messages. The identification of the problem of illness will also result in changes in emotional state. For example, perceiving the symptom of pain and receiving the social message that this pain may be related to coronary heart disease may result in anxiety. Therefore any coping strategies have to relate to both the illness cognitions and the emotional state of the individual (131).

The next stage in the SRM is the development and identification of suitable coping strategies, Coping can take many forms, however two broad categories of coping have been defined that incorporate the multitude of other coping strategies; approach coping (for example, taking pills, going to the doctor, resting, talking to friends about emotions) and avoidance coping (eg denial wishful thinking) When

faced with the problem of illness the individual will therefore develop coping strategies in an attempt to return to a state of health normality (131)

The third stage of the SRM is appraisal. This involves individual's evaluating the effectiveness of the coping strategy and determining whether to continue with this strategy or whether to opt for an alternative one (131).

3.6.7 The COM-B Model

Complex interventions can present challenges in their ability to identify the active, effective components within them. A well-specified intervention is essential before evaluation of effectiveness is worth undertaking as an under-specified intervention cannot be delivered with confidence of rigor and, if evaluated, could not be replicated (133). The COM-B Model is a more recent framework in which capability, opportunity and motivation are considered a focus in designing behaviour change interventions (134) Table3.5. The use of frameworks such as the Behaviour Change Wheel to guide intervention development is relatively new in behaviour change research and wasn't standard practice when the HF2 intervention was being developed,

Table 3:5 Three essential components in the hub of the Wheel of Behaviour Change

• Capability: *the psychological or physical ability to enact the behavior*
• Opportunity: *the physical and social environment that enables the behaviour*
• Motivation: *the reflective and automatic mechanisms that activate or inhibit behavior*

These three essential components are contained in the hub of the Wheel of Behaviour Change which in turn has nine intervention functions aimed at addressing deficits, *education, persuasion, incentivisation, coercion, training, enablement, modeling, restrictions and environmental restructuring* in one or more of these three conditions, around these are placed seven categories of policy that could enable those interventions to occur; Environment/social planning, communication/marketing, legislation, service provision, regulation, fiscal measures and guidelines (134).

The COM-B system seeks to characterise behaviour change interventions and link them to an analysis of the targeted behaviour thus improving the design, implementation and evaluation of future behaviour change intervention practice (134). This model draws from many models the important factors required to predict behaviour intention and facilitate behaviour change across many societal domains. It has been shown that the framework can be implemented in a variety of behaviour interventions such as improving hand hygiene in hospitals to improving the environment by reducing litter (135) Figure 3.2.

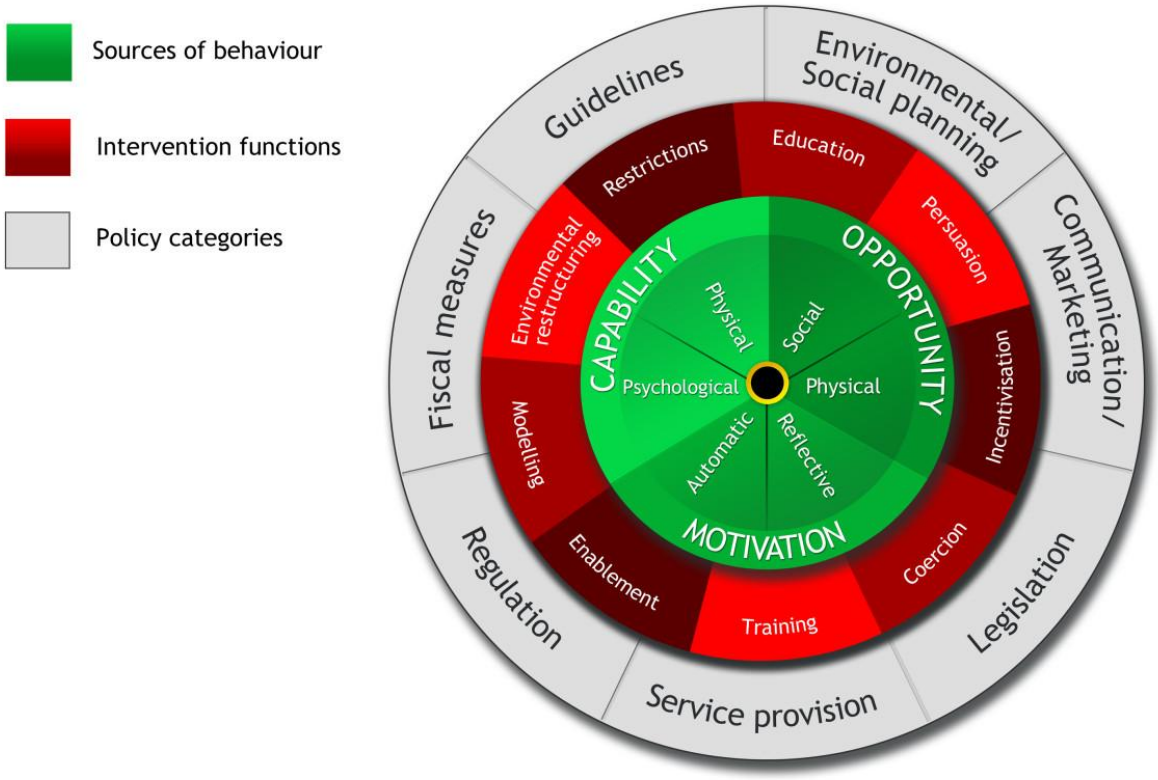

Figure 3:2 Michie S, et al. (2011). The behaviour change wheel

3.7 Behaviour Change Techniques

Behaviour Change Techniques are theory based methods used in interventions to change one or more determinants of behaviour such as attitudes toward certain behaviours. They were developed in response of necessity to clarify the difference between behaviour change methods and the practical applications of these methods.

Evaluation of the findings from behaviour interventions are required in order for behavioural science to move forward. The methods used in the course of the interventions are required to be described in order to identify which interventions work. Previously there had been no common terminology in place to describe the

methods used to identify effective behaviour change methods, which made it difficult to evaluate and accurately replicate the intervention content. Intervention mapping was developed in response to the lack of theoretical frameworks by which to design health promotion programs (136). It provided a taxonomy of six behaviour change methods which could be used to interpret intervention content (137). More recently the Com-B model has provided a framework and "The taxonomy of behaviour change techniques" by Abraham and Michie (134) provided a standardised terminology which enabled intervention designers to review interventions, and identify which components were effective and which were not (136).

3.7.1 Motivational Interviewing

Motivational Interviewing (MI) is "grounded in a respectful stance with a focus on building rapport in the initial stages of the counseling relationship" (138). A central concept of MI is the identification, examination, and resolution of ambivalence about changing behaviour. It was first developed by William R. Miller in 1983 in response to his experience with problem drinkers. Motivational Interviewing is a collaborative, goal oriented means of communication with a focus on change. It is designed to strengthen an individual's motivation for and movement toward a specific goal by eliciting and exploring the person's own arguments for change. MI is guided by five basic principles;

- express empathy
- avoid argument
- support self-efficacy
- roll with resistance
- develop discrepancy (138)

MI has been cited and used extensively in recent behaviour change interventions (139,140). Studies involving MI as a technique have shown good support in successful outcomes for increasing physical activity (141,142,143), reduced calorie intake (143) and decreased BMI (143,144) although these studies durations had not gone beyond six month follow up and evaluation of maintenance. More studies are required to further explore the longer term effects (145).

3.7.2 Techniques Used in Motivational Interviewing

Providing empathy from different sources i.e friend family health professional can offer an all-round perspective of their situation. Clarifying goals (feedback should be compared with a standard (an ideal), and clarification of the ideal can provide the pathway to the goal) active helping (such as expressing caring or facilitating a referral, all of which convey a real interest in helping the person to change (146). Giving advice and educational materials with regard to specific behaviours requiring change and discussion around removing barriers, providing choice clarifying that if an individual chooses not to make change then it is their right to make that choice, facilitating change should be encouraging and not insisted upon (146).

3.7.3 Goal setting

There is evidence to support the concept that setting specific goals at the beginning of an intervention is important. Setting specific goals to achieve behaviour change leads to higher performance when compared with individuals who have only vague goals or no goals at all (147). "The use of goal setting is more successful when the goals are specific in outcome, proximal in terms of attainment and realistic in terms of an individual's capabilities"(116). Setting goals at the right levels for people will

help to increase self-efficacy, and providing regular feedback on goal attainment is important in attaining a sense of learning and mastery.

Bandura's Theory suggests four sources of self-efficacy that can be drawn on and incorporated into intervention strategies to enhance self-efficacy (148). The source with the greatest potential for increasing self-efficacy is mastery experience, which entails having a person successfully achieve a goal which is proximal and reasonable e.g. substituting fruit for a high calorie dessert or being able to walk a mile.

A review of face to face communication behaviour techniques in a primary care setting found goal setting was not as successful as behavioural counselling, motivational interviewing, education and advice (149). These techniques were successful in some of the studies reviewed but these techniques were also used in the less successful studies reviewed, due to the differences in context, study design and patient population. However, overviews of evidence for behaviour change techniques, found more favourable support for goal setting (150). This review highlighted the need for better described theoretical structure to enable reviewers understand which techniques are working, and better described methodology so that intervention length and intensity can be examined.

In weight management interventions the quantitative analyses in this particular review did show the importance of formulating a program goal specifically towards weight management as those interventions were found to be more successful than interventions that had more broadly defined program goals (e.g. prevention of cardiovascular disease or improving general health status). The results of meta-analysis also indicate the importance of executing a formative or process evaluation in addition to assessing effects of the intervention on primary outcomes. Formative evaluation enables the intervention designers to guide programme development or

to adapt the intervention as a consequence of identified barriers of successful implementation (151).

3.7.4 Self-Monitoring

The aim of self-monitoring is to increase the individual's awareness of physical cues and/or behaviours and to help identify barriers to changing behaviour. Self-based monitoring allows the individual to assess progress within the intervention on their terms, removing barriers such as travel or scheduling constraints associated with structured group program (152). The person is provided with self-monitoring strategies which are applied in conjunction with external prompts.

Evidence supports the importance of self-monitoring in achieving behaviour change in both physical activity and weight loss in both observational and clinical trials. Meta analyses found that studies using self-monitoring in both physical and weight loss interventions were twice as likely to be successful in reducing weight, (153) this effect was shown to be larger in physical activity intervention studies (154). Tools to facilitate self-monitoring as a behaviour technique, include walking records, five - a-day diary to record fruit and vegetable intake, a weight log book to monitor weight loss and progress charts to monitor relapse prevention.

3.7.5 Feedback and reinforcement

Providing feedback helps facilitate learning of new dietary or physical activity behavioural skills by providing an external measure against which to assess their progress (155). Having established goals and providing feedback on level of achievement enables the individual to set realistic goals for future improvement.

An overview of behaviour techniques in 210 studies showed an inconsistency in results for three health behaviour outcomes diet, physical activity and smoking. The results varied as with some studies very few techniques were performed. However, positive results for techniques directed towards reinforcement in studies on diet and exercise were shown to be successful 46% over all the health behaviours. This report again highlighted the continued insufficient reporting of the content of interventions the limitation of this review is that it was heavily biased toward smoking cessation (150).

An overview carried out of the effectiveness of behaviour change techniques concluded that self-monitoring of behaviour, prompting specific goal setting, providing feedback on performance, and review of behavioural goals in interventions designed to promote healthy eating and physical activity to be effective (156). This mega regression was found to be the most robustly carried out analysis of behaviour techniques found in the literature to date.

3.7.6 Conclusions

The evidence from the search of the literature undertaken to inform this investigation concludes that in order to design, implement and evaluate the effectiveness of a weight loss intervention and to instigate a change in health risk behavior, many variables need to be addressed, these are outlined in Table 3.8. This equates to a large body of literature to be considered and evaluated and it is not within the scope of this thesis to cover all aspects of health risk behaviour.

Table 3:8 Considerations when planning weight loss interventions

- who to target: individuals/populations
- what to target: single or multiple behaviours
- which theories/models to use
- which behaviour techniques to use
- length of intervention and follow up
- cost effectiveness
- settings

Lifestyle risk communication can be a powerful motivator and equally can discourage people from making essential changes in health behaviour if change is viewed as an impossible task. The literature shows there are health professionals still not taking advantage of opportunistic situations to convey health risk from poor diet and inactivity, sometimes as a result of lack of knowledge, lack of time and resources but sometimes also through lack of confidence in ability to bring about the necessary change in an individual (157,158).

The HF2 study design is underpinned by two theoretical frameworks; The Transtheoretical Model of Behaviour Change, (The Stages of Change Model: SOC) and The Theory of Reasoned Action (TRA) described previously in sections 3.6.3 and 3.6.4. Behaviour techniques to be used include goal setting, self-monitoring, feedback and reinforcement, development of self-efficacy, relapse prevention, enlisting social support, overcoming barriers, decision balance discussion, pros and cons of change.

4. Methodology

4.1 *Study/trial design*

The study was a two-arm randomised comparison study which compared the HF2 intervention with usual care i.e. the standard brief intervention provided at the TASCFORCE screening. HF2 was a nested cohort within the TASCFORCE study.

4.2 Inclusion/Exclusion Criteria

4.2.1 *Inclusion*

Participants who had taken part in the TF CVD risk screening study, 40 years old and over, with a BMI ≥ 25kg/m2, had no known cardiovascular disease or ill health and had given informed consent to take part in HF2.

4.2.2 *Exclusion*

Participants who had failed screening criteria for TF, e.g. found to have hypertension, CHD risk score ≥20 (based on Framingham Risk Score) (159) or previous serious illness requiring ongoing follow-up.

4.3 Study Population

4.3.1 *Geographical Distribution*

Tayside region is situated in the north east of Scotland. It covers an area of 7508 sq km, comprises of three local authority areas, Angus, Dundee City and Perth & Kinross and had an estimated total population of 411,750 mid 2012 (160).

4.3.2 *Angus*

Angus is largely remote, with rural glens, small market towns and busy coastal towns, which contain around half of the 116,210 population. Most of the Angus population are found in the middle decile SIMD classification; however, the most deprived area in Angus is the coastal town of Arbroath which is amongst the 10% most deprived areas in Scotland (161).

4.3.3 *Dundee*

The Dundee City area covers 62 square kilometers, and is geographically the smallest local authority area in Scotland but has the largest population estimated to be 147,800. It is bordered by Perth and Kinross to the west and by Angus to the north and east (160). The proportion of Dundee's population whose lives are affected by poverty and who are classed as socially excluded is almost the highest in Scotland, exceeded by only Glasgow and Inverclyde.

4.3.4 *Perth and Kinross*

Perth and Kinross is the fifth largest geographical area in Scotland it has an estimated population of 147,740 with almost one third of the population living in Perth. It also has the third highest level of migrant workers in Scotland, after Edinburgh and Glasgow. It is a diverse area comprising of a number of small communities, each with its own distinct challenges and opportunities, remote communities like Kinloch Rannoch pose many challenges in terms of access to, and delivery of, essential services including basic infrastructures such as water supplies

(160). Figure 4.1 shows a map of the Tayside area signified by the pale and dark green shaded areas of Perthshire, Dundee, Angus and East Fife.

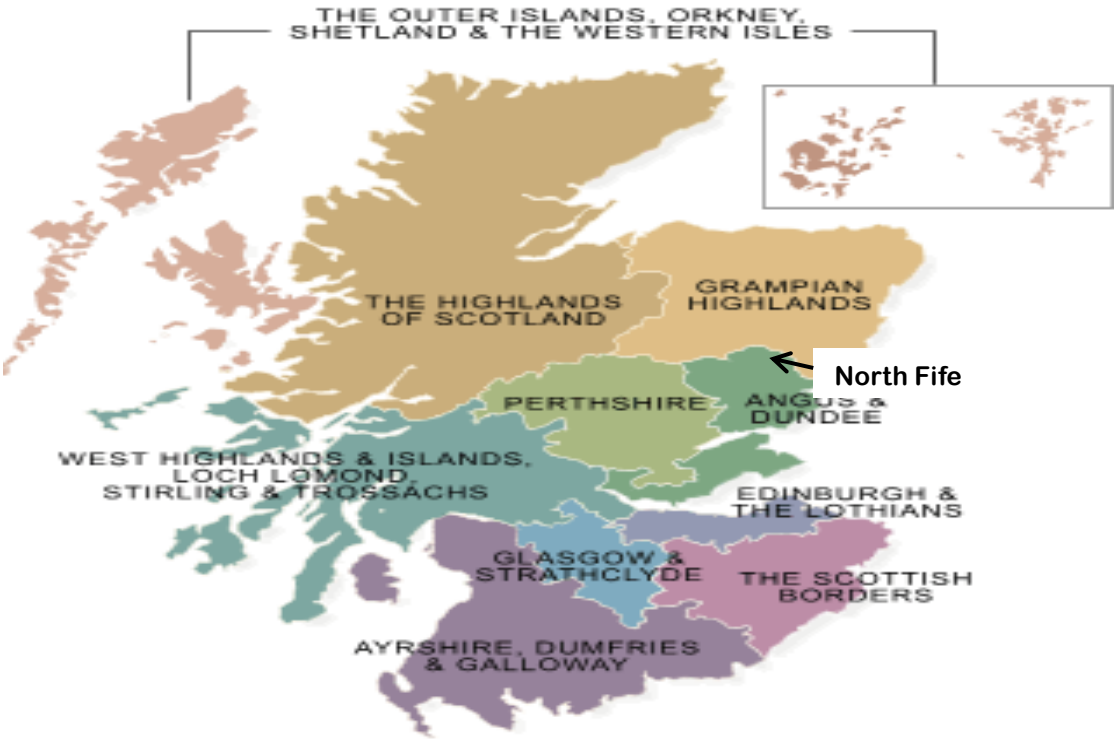

Figure 4:1Map of Tayside Area

4.4 *Recruitment Strategies*

Tayside has a diverse population in both rural and urban areas from which to recruit participants into the HEALTHFORCE2 study (HF2). The primary methodology was a randomised comparison trial from a nested cohort sample of the TASCFORCE (TF) study, participants were recruited into a two arm randomised comparison trial. Recruitment took place between April 2011 and March 2012 (first period - 12 months), then September 2012 and November 2012 (second period – 3months).

Recruitment initially began with local newspaper advertising and a request for healthy volunteers to take part in the cardiovascular risk screening program

TASCFORCE. This approach provided an initial list of volunteers which started the TASCFORCE Project and from which HF 2 participants would subsequently be recruited. The list increased through word of mouth as more volunteers presented.

A second strategy was deployed which aimed to recruit employees from local businesses, local authority departments and educational institutions (Table 4.1).

The decision to travel into workplaces proved productive and visits over a period of several months to some workplaces were organised to facilitate recruitment. Volunteers recruited from workplaces in some instances travelled large distances across Tayside which increase the sample's geographical diversity.

The final recruitment strategy involved approaching several GP practices within the Tayside area. Administrative support and resources from the Health Informatics Centre (HIC) within the University of Dundee provided assistance, liaising with GP practices to select healthy volunteers from their patient lists and mailing study invitation letters.

Table 4:1 Workplace Recruitment Sites

Workplace	Area Recruited in Tayside
Stagecoach Group	North Fife, Perth & Kinross, Angus and Dundee
St Columba's High RC School	Perth
Menzieshill High School	Dundee
Dundee College	Dundee
Angus College	Arbroath
University of Dundee	Dundee
University of Abertay	Dundee
The James Hutton Institute	Dundee
Scottish and Southern Energy	Perth and Dundee
Scottish and Southern Water	Dundee
AVIVA Insurance	Perth
Perth Local Council	Perth
Dundee Fire and Rescue Services	Dundee
GP Practices	Dundee Angus and Perth
Tesco Stores and Call Centres	Dundee
NCR	Dundee

4.5 Screening Visit

4.5.1 *Screening and CVD Risk Perception Questionnaire Completion*

Prior to cardiovascular screening, all study participants received the standardised TF participant information leaflet (PIL) (Appendix D) with a separate PIL describing the HF2 study (Appendix E), and invited to provide informed consent to both. All participants were then invited to complete the pre-cardiovascular risk perception questionnaire (Appendix F). The questionnaire was designed purposely for the HF2 study as the investigator was unable to source an appropriate validated questionnaire specific to the question asked. The question was designed to illicit a response with regard to participants own risk perception, "Compared with a person of your own age and sex, how would you rate your risk of having a heart attack or stroke in the next 10 years?"

Participants were asked to make a choice from the following answers:

- Much lower than average
- Lower than average
- Average
- Higher than average
- Much higher than average

Post-screening all participants received the brief lifestyle intervention (usual care) and then invited to complete the post-cardiovascular risk perception questionnaire asking the same question as at pre-screening (Appendix G).

4.5.2 *Eligible HF2 Participants*

Participants with a BMI ≥ 25kg/m2 who wished to take part in the HF2 study were then informed that questionnaires would be mailed out to them within two weeks. These would assess baseline dietary intake, physical activity, general health and demographic information. The questionnaires were in three parts and selected for ease of use, they were designed not to be too arduous for participants to complete:

- Part 1 assessed Quality of Life (QOL) and was based on the Short Form Health Survey (SF-12) (Appendix H) the short version of the SF-360 (162). It was used in the HF2 study to measure of participants self-perceived health state and quality of life and pre and post intervention or usual care, see section 4.6 for further details of all questionnaires used.

- Part 2 assessed dietary intake (Appendix I and J) using the Dietary Instrument for Nutritional Education (DINE)(163), and the Five a day Community Evaluation Tool for assessing fruit and vegetable intake FACET appendix I) (164). This questionnaire was used to evaluate differences between groups with regard to changes in modifiable risk factors and physiological measures such as weight, BP, blood lipids and CVD risk score.

- Part 3 recorded physical activity levels and was evaluated using the International Physical Activity Questionnaire (IPAQ) (Appendix K) short questionnaire (165). It was used to assess between group changes in physical activity levels and views on initiating and maintaining changes in physical activity.

4.5.3 *Support for participants in exclusion criteria for HF2*

Participants who were not eligible for HF2 at screening but were receptive to additional advice and support were directed to other sources of health information in the community, for example; written educational material provided as booklets from British Heart Foundation and their own GP services. In the case of participants wishing to discuss their health concerns with their own GP the study team alerted the GP in advance via letter that the participant may present for consultation. Individuals were given the opportunity to decline to consent from taking part in the HF2 study and this would not have prevented them from taking part in the TF screening. Ethical approval for the study had been received from NHS Tayside Committee for Medical Research Ethics.

4.6 Details of Questionnaires Administered to HF2 Participants

4.6.1 *Quality of Life Questionnaire (SF12v2)*

The SF-12v2 questionnaire is designed to assess the quality of an individual's life across a broad range of specific areas. This questionnaire has been validated to be used in evaluating the effectiveness of health related interventions in clinical practice and research and can indicate areas of an individual's life that may benefit from modification (166). The SF-12v2 is a generic measure and does not target a specific age or disease group. It provides a shorter, yet valid alternative to the SF-36, which has been seen by many health researchers as too long to administer. It is

weighted and summed to provide easily interpretable scales for physical and mental health.

Physical and Mental Health Composite Scores are computed using the scores of twelve questions and range from 0 to 100, where a zero score indicates the lowest level of health (162). Data derived from the questionnaire is entered into the Quality Metric Health Outcomes Scoring Licensed Software 4.5 where the reports are generated.

4.6.2 *Physical Activity Questionnaire*

Physical Activity levels were determined using The International Physical Activity Questionnaire (IPAQ). The IPAQ was developed to measure health-related physical activity in populations. The short version of the IPAQ used in the HF2 study has been tested extensively and is now used in many international studies. It was developed in 1996 to provide a valid and reliable questionnaire measuring health-related physical activity suitable for both research and surveillance (165). The first part of the questionnaire gathers information with regard to number of days, hours and minutes per week spent undertaking levels of vigorous, moderate, walking and sedentary activity. The second part of the questionnaire uses questions both dichotomous and within a possible range to gather data on participants confidence and readiness to initiate and maintain physical activity change. The data is then presented into participants levels of confidence and stage of readiness to initiate change (Appendix K).

4.6.3 *Dietary Questionnaires*

4.6.3.1 *FACET*

Finally dietary intake was assessed using the Five A-Day Community Evaluation Tool (FACET). The FACET questionnaire (Appendix I) was designed and piloted in 2001 by the MRC Dunn Nutrition Unit, Cambridge and the University of Dundee for the purposes of assessing the effectiveness of five-a-day activities nationally. The questionnaire was intended for use by non-nutritionists working in the field of primary health care. During the pilot study it was found that there was a positive correlation between the intakes assessed by FACET and those assessed by a more detailed food diary method (164). The survey continues to be recommended by the Department of Health as an evaluation tool. The questionnaire asks participants to indicate by ticking a box on a five point scale (0 – 4+) the number of portions of fruit and vegetables eaten within the last 24 hours. Analysis involved calculating the total number of portions consumed each day.

4.6.3.2 *Dietary Instrument for Nutrition Education (Dine)*

The Dietary Instrument for Nutrition Education (DINE) Appendix J (163) was designed and validated by the Department of Primary Care at Oxford University. It is a brief, structured dietary questionnaire which attempts to make a brief assessment of an individual's fat and fibre consumption. Validation of this questionnaire was carried out in 1994 against a four day detailed diet record; and the groups of foods included in the questionnaire were based on the 1989 Annual Report of the National Food Survey Committee (167). The DINE questionnaire is still frequently used by health professionals and a section within it has been adapted for use in the Health Survey for England and the Scottish Health Survey (Appendix J). Groups of foods

with a similar nutrient content and dietary use are combined; each group of foods is assigned a score proportional to the fat or fibre content of a standard portion size. The scores are weighted by the frequency of consumption using four categories which range from "less than once a week" to "six times a week or more"; more frequently eaten foods are categorized on a daily basis. The classification of fat and fibre are low, medium, or high (168).

4.6.4 *Demographic Questionnaire*

Participants were also sent a questionnaire to capture demographic characteristics including ethnicity, educational attainment, employment and marital status (Appendix L). The questionnaires were sent by post approximately 2 weeks from consenting to participate in the study and participants were provided with freepost envelopes to return the questionnaires.

4.7 Randomisation

On receipt of completed questionnaires participants were randomised to intervention (Group 1) (Appendix M) or usual care (control) (Group 2) (Appendix N). Participants were randomly allocated 50% to intervention and 50% control in blocks of 4 using SPSS (Version 18). The investigator was blinded to the participant's group allocation and a second investigator conducted the randomisation and contacted the participants by letter to inform them of their group allocation.

4.8 Outcome Measures and follow up

Measures at all outcome points were completed face-to-face excluding the questionnaire data which was self-reported and mailed back via freepost envelope

by participants. Details of the outcomes collected at the different time points are detailed in Table 4.1.

Table 4:1 Outcome Measures: (B = Baseline F = 4 months follow-up)

	Measure	Point
Primary Outcome		
Body Weight (Kg) BMI (Weight and Height) (kg/m2)	Calibrated combined Seca Scales and Stadiometer	B, F
Secondary Outcome		
Waist Circumference (cm)	Tape Measure	B, F
Lipid Profile (mmol/L)	Venous sample whole blood	B, F
Blood Glucose (mmol/L)	Venous sample whole blood	B, F
Cardio-Vascular Risk Assessment	Venous sample whole blood	B, F
Blood Pressure (mm Hg)	eSecureAneroid Sphygmomanometer	B, F
Diet	DINE / FACET Questionnaires	B, F
Physical Activity	IPAQ Short Questionnaire	B, F
Cardio-Vascular Risk Perception	Cardio-Vascular Risk Perception Questionnaire	B
Quality of Life	SF12 Questionnaire	B, F
Program Acceptability	Exit Questionnaire	F

4.8.1 Anthropometric Measurement

4.8.1.1 *Weight, BMI and Measures*

All anthropometric measures were carried out on annually calibrated equipment within the Clinical Research Centre. Weight and height were recorded and BMI

calculated using a "Seca 703 Wireless 360 High Capacity Digital Medical Scale" (Appendix O), values were recorded to one decimal place. Body Mass Index (BMI) is an index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in meters (kg/m2) (169).

4.8.1.2 *Height*

Height was measured to two decimal places using a portable "Seca Leicester Stadiometer" (Appendix O). Participants were asked to remove their footwear and stand with a straight back against the metered device.

4.8.1.3 *Waist Measures*

Waist measurement was measured in centimeters to one decimal place at the midpoint between the lower margin of the last lower rib and the top of the iliac crest, using a stretch-resistant tape. The recommended gender specific cut-off points of 94 cm for men and 80 cm for women for increased risk, and 102 cm for men and 88 cm for women for substantially increased risk were used (194).

4.8.1.4 *Blood pressure measurements*

Baseline blood pressure measurement was carried out using an "eSecure - Aneroid Sphygmomanometer Monitor Meter" (Appendix O). Participants were seated for 10 minutes post introduction to study and informed consent, and prior to blood pressure measurement. The arm was extended to a 45 degree angle and two readings were taken, the mean of the two was recorded. All measurements were

carried out in accordance with localized Standard Operating Procedures within the Clinical Research Centre

4.8.1.5 *Blood Sampling*

During the initial TF screening visit participants consented to provide non-fasting samples of venous blood where possible drawn from the antecubital fossa. From these samples a full cholesterol profile was calculated and blood glucose measurement obtained. All blood samples were processed using the * Alere Cholestech LDX Analyser (Appendix O) which calculated CVD risk based on the Framingham risk score calculation (170). Results were available in five minutes.

4.8.1.6 *Cholestech LDX*

Each member of the research team involved in screening participants were given full training in operating and interpreting the results by the training department of "Inverness Medical" supplier of the analyser. Prior to screening, daily checks were performed on the **Cholestech LDX to determine if the analyzers "optics" were functioning and a print out of each optics check was logged. Monthly calibration checks were also carried out using live assays to ensure accurate results using a "Multianalyser Kit" (Appendix O) supplied by Alere.

For the duration of the Tascforce study, at six monthly intervals participant samples were sent to Ninewells Hospital biochemistry laboratory (once TF results were obtained) for further verification of calibration accuracy. Results measured cholesterol within the same bias and accuracy as commercial laboratories.

A 10 year CVD risk was calculated by the "Cholestec LDX Analyser" prior to randomisation based on the individuals lipid profile, age, systolic blood pressure,

current smoking or non-smoking and gender. The device has been validated for people between the ages of 30 – 74 with no known CVD (171). The Medicines and Healthcare Products Regulatory Agency (MHRA) concluded in their evaluation of the Cholestec LDX Aanalyser that sensitivity and specificity for detecting high risk individuals on total cholesterol alone were 73% and 100% respectively.

If the ratio of total cholesterol to HDL cholesterol was used, then sensitivity improved to 80% and specificity slightly reduced to 98% it was also stated that the device was “simple to use and gave results comparable with those obtained by using a laboratory instrument" (171).

**Alere Cholestech LDX®*

The TC HDL GLU Cassette measures total cholesterol (TC), a measure of the total amount of cholesterol in the blood, and high density lipoprotein (HDL) cholesterol (referred to as the "good cholesterol") as well as glucose (GLU), a measure of blood sugar. TC HDL GLU also calculates the TC/HDL ratio and non-HDL cholesterol.

* *The Optics Check Cassette performs a test on the Cholestech LDX to determine if the Analyzers optics are functioning properly.

4.9 *HF2 Intervention Group*

Each month following randomisation the intervention group participants received a telephone call and lifestyle information pack. Appendix P shows the introduction letters provided to participants outlining the structure for the subsequent month's telephone call with their counsellor. (Full details of the intervention are described in section 4.11.2). Telephone calls were scheduled for 1 week following the arrival of the information pack. Further details of the structure of the telephone consultations and call schedule are outlined in Appendix Q.

4.10 Follow-Up

Prior to the four month follow-up appointment both groups received repeat questionnaires to enable a comparison with baseline questionnaire data. These were returned using the freepost envelope. A courtesy call was given the day prior to appointment to help minimise loss to follow up. The 30 to 40 minutes follow-up appointment took place in the Clinical Research Centre at Ninewells Hospital (Figure 4.2)

Figure 4:2 Clinical Research Centre, Dundee

A sample of venous blood was obtained to calculate cholesterol and blood glucose levels, blood pressure was measured and weight, height and waist measurements obtained to calculate (BMI) using the same methods previously outlined in section 4.8. These repeat measures were replicated to enable an accurate comparison from baseline data. Participants were given the opportunity to discuss the results with the study nurse.

4.11 The Two Study Arms

4.11.1 *Control arm: Brief intervention (usual care)*

The usual care brief intervention given to all 314 participants took between 10 and 20 minutes. Discussion was led by the results from the lipid evaluation and the number of lifestyle factors requiring discussion with the individual participant.ie smoking, waist measurement, BMI, diet and levels of physical activity. British Heart Foundation booklets (172), explaining types and acceptable levels for lipids, blood sugar, how diet and physical activity affects weight, CVD risk and cholesterol, were given to both the control and experimental arm as added information to enhance participants understanding and motivation to consider improving aspects of their health.

Following this brief intervention participants were randomised to either follow- up only (control group - usual care), or the multiple contact intervention. Participants randomised to the (control group - usual care) had no contact until follow-up visit at 4 months.

4.11.2 *Experimental arm: Brief intervention (usual care) plus Multiple contact intervention (HF2)*

Social Cognitive Theory underpins the delivery of the HF2 intervention improving self-efficacy through behavioural techniques namely goal setting, self-monitoring, incentives, feedback and reinforcement. The HF2 Intervention was delivered by telephone over four monthly contacts by trained lifestyle counsellors who were experienced in using these behavioural techniques and had prior experience in using motivational interviewing techniques.

The focus of contact 1 was increasing levels of physical activity, with the aim to achieve a minimum increase of 150 minutes per week of physical activity. Contact 2's focus was to increase fruit and vegetable intake, to achieve a minimum increase of at least 1 portion per day (towards reaching the current target of 5 portions of fruit and vegetables per day). Contact 3's focus was to achieve a weight loss of 7% (which had been demonstrated to be clinically effective with respect to diabetes prevention) (129) from baseline. The weight loss target was a focus throughout the HF2 intervention however it was discussed in more detail in this stage. Contact 4's focus was relapse prevention and avoidance of weight gain. Each stage supported consolidation of the previous stages Figure 4.3 demonstrates the flow of the telephone consultations.

4.11.2.1 *Incentives and Self-Monitoring*

Each contact began once the participant had received the mailed lifestyle information packs, motivational tools were included in each of the four packs to support and incentivise change based on the particular monthly theme i.e. apple corer, vegetable steamer, for dietary changes, pedometer for physical activity

changes, tape measure for self-monitoring waist circumference and an alcohol wheel, to measure alcohol and calorie intake.

In order to facilitate self-monitoring as a behavior technique, participants were provided with a walking record to complete for the duration of the intervention, a five – a - day diary to record fruit and vegetable intake, a weight log book to monitor weight loss and a "top 10 tips" progress chart to monitor relapse prevention. An external prompt such as follow up from counselors with a monthly 30 minute telephone call encouraged continued self-monitoring as each telephone contact provided discussion from the previous months behavior change focus which also established a routine to the intervention.

4.11.2.2 *Goal Setting, Feedback and Reinforcement*

The focus of each follow up telephone counselling session was based on the information received for that month. Achievable goals were discussed and defined with the participant for example identifying small changes opportunities and activities for consideration in their local area. Planning what they will do (where and when) and setting a goal for week one, going through current physical activity guidelines and discussing discrepancies between guidelines and what they are actually doing and discussing ways of overcoming barriers to becoming more active. Each telephone contact provided feedback and reinforcement from the previous months behaviour change focus as providing feedback on current level of achievement enables the individual to continue to set realistic goals for future improvement (147).

4.11.2.3 *Increasing Motivation and Self-Efficacy*

Information regarding diet, physical activity and anthropologic measurements gathered from the initial screening visit (usual care) was used to make comparisons with any behaviour changes made at each telephone call to increase motivation and self-efficacy. Identifying perceived achievements and continually reevaluating participant's confidence and motivation, discussing and identifying barriers to change and ways of overcoming these were considered at each contact. Participants were also encouraged to seek social support from partners or a particular friend or family.

4.11.2.4 *Pros and Cons of Change/ Decision Balance*

The HF2 counsellors facilitated participants to reach a decision balance by encouraging them to consider the pros and cons of making behaviour changes, including the risks of being overweight/obese and benefits of a healthy weight. Educational printed material was provided to support the decision making i.e. images describing the impact of weight loss/gain on CVD risk, fruit and vegetable literature which included recipes, healthy weight literature e.g. portion control, snacking, 10 top tips for a healthy weight leaflet, local group/community activities were also described and contact information provided for activities such as walking groups, healthy eating groups, weight reduction groups.

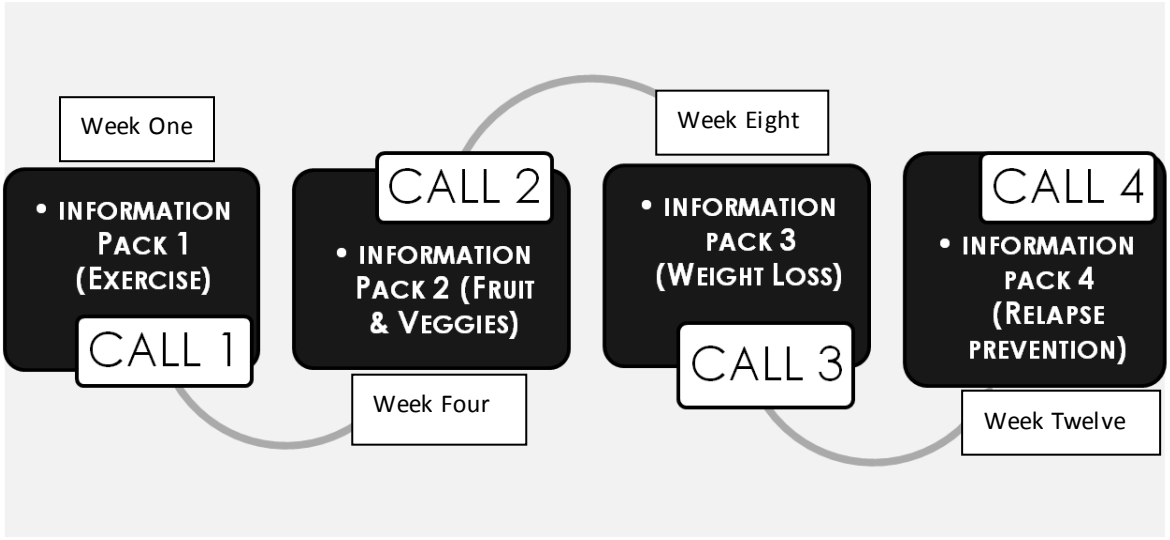

Figure 4.3 Structure of telephone calls

4.12 *Randomisation*

The target recruitment figure was 314 participants, 157 in both control and intervention groups. This figure was based on the data from HF to show a 7% change in body weight at 80% power (173). The sample size calculation is described in section 5.1.1. Participants were randomly allocated 1:1 to either HF2 intervention or control on receipt of completed questionnaires. A researcher independent of the analysis of study outcomes randomly allocated participants in blocks of 4 using "The Statistical Package for the Social Sciences "(SPSS v18). Analysis was carried out blind until all study outcomes were complete. It was necessary to add a second recruitment phase as a number of participants were unable to commit to follow up visits for a variety of reasons, mainly other family commitments making it difficult to arrange appointments. A short second recruitment and follow up period was introduced which successfully preserved statistical power.

4.13 Statistical Analysis

4.13.1 *Primary Outcome*

The study was powered to a detect weight loss of 7% and intention to treat analysis (ITT) was carried out on the primary outcome only. Baseline and follow up data was described using means, percentages and standard deviations. Independent T tests were used for comparing differences between groups for quantitative data and general linear model univariate analysis applied to control for baseline weight and randomised group. Paired T tests were used for within group differences. Regression modelling was used to explore which factors may have independently or in combination have had an influence on weight loss. General linear modelling was used to test each variable independently, as it can additionally test for categorical predictors. Where variables were found to be significant predictors of weight loss ($p=<0.05$) these significant predictors were in turn entered into a two-variable model with non-significant variables being removed from the analysis. The process continued resulting in a three variable model where all variables and interactions in the model were significant ($p=<0.005$), SPSS v21 and v22 were used for the calculations.

4.13.2 *Secondary Outcomes*

Secondary outcome data was analysed using data from only those subjects who completed the study (Per Protocol). The main analysis involved standard two sample comparisons (parametric or non-parametric as dictated by the distribution of the data). Descriptive summaries of baseline and follow up data were tabulated. Results were reported as mean/standard deviations, medians/inter-quartile ranges, p values

and confidence intervals.

Paired t-tests were used within groups to check for differences from baseline to follow-up and independent t tests for changes between groups at baseline and follow up. Categorical variables were analysed with Pearson chi-squared tests where appropriate. Demographic, physiological and anthropometric data was compared to assess change in modifiable risk factors, and questionnaire data to assess change in diet, physical activity, self-reported health status and perceived CVD risk were analysed using Pearson chi-squared tests.

4.14 *Blinding*

Research staff involved in participant recruitment and follow-up visits were not involved in delivery of the intervention. Questionnaires were anonymised using ID numbers and sequential study participant numbers. Entry of baseline and follow-up data and analysis of data was carried out by the investigator who did not have contact with the participants until the four month follow-up visits. The investigator remained blind to group allocation by asking participants not to disclose which group they were allocated to at the follow up visit and until statistical analysis was complete. A second study investigator was responsible for randomisation and had no input into data entry.

4.15 Dealing with missing data

It is important to account for the effect of missing data from the proportion of participants who did not complete the study. Missing data can lead to bias and exclusion of a significant proportion of the original sample, which in turn can cause a substantial loss of precision and power. In order to preserve power and eliminate

bias a Multiple Imputation method of dealing with missing data was adopted for the ITT analysis. This method gave a best estimate of what the actual missing values were likely to have been, and reassurance that bias from missing data had been accounted for (Appendix R).

4.15 Data handling and Record Keeping

All data was handled according to good clinical practice (GCP) requirements and entered on to a computerised database at the University of Dundee. All data was identified via a unique participant ID and data tables were linked using this number. The names and addresses of subjects matched to their trial number were stored in a separate secure database. All databases were password protected and stored according to the requirements of the Data Protection Act 1998.

5. Results

5.1 Results (1) Recruitment and Retention

5.1.1 *Recruitment*

The TASCFORCE Project and the Healthforce 2 study aimed to recruit healthy volunteers aged between 40 and 75 years, with an equal distribution of SIMD classification. A decision to travel into workplaces to recruit proved productive and volunteers recruited from workplaces were drawn from a wide cross section of Tayside which increased the sample's geographical diversity. Recruitment strategies proved successful in attracting the target of 5000 participants over five years into the TASCFORCE Project and provided the cohort from which HF2 participants were recruited.

A consort diagram (figure 5.1) shows progression of the HF2 study through recruitment, enrolment and follow up. Volunteers were enrolled from 13th April 2011 to 29th March 2012 (first period), and 3rd September 2012 to 13TH November 2012 (second period). This second period was necessary due to a higher than expected attrition rate of participants from the initial recruitment period, reducing the numbers completing to below the minimum required for statistical power.

To demonstrate a 7% weight loss with 80% power, n=230 participants 115 from each group, would be required to complete the study. An extra 15% (n=264) were initially randomised to allow for potential drop-outs, but when this was found to be insufficient, this was later increased to 37%, such that n=314 were ultimately randomised (157 in each group).

A total of 1134 TASCFORCE volunteers were screened in the HF2 recruitment periods: 770 (67.9%) fulfilled the eligibility criteria to take part in HF2, 364 (32.1%) did not (BMI ≤25kg/m^2). Of those eligible, 438 (56.9%) accepted and 332 (43.1%) declined to take part. One hundred and twenty four people were excluded from randomisation for the following reasons: seven questionnaires were not sent back within the allotted time frame of less than three weeks, 23 questionnaires were returned after randomisation was completed, and 94 failed to return questionnaires.

A total of 314 people were randomised to take part in HF2, 157 were randomised to intervention and 157 to control. Despite efforts to arrange suitable appointments, of the 314 participants randomised, 24 (7.6%) from the intervention group and 11 (3.5%) from the control group informed the study team of their wish to withdraw from further participation in the study. A further 16 (5.1%) from intervention and 17 (5.4%) from control were considered lost to follow up as they did not notify the team of an intention to withdraw. Two attempts were made via telephone to each of the participants considered lost to follow up. Messages were left on answer machines asking participants to contact the study team to arrange a follow up appointment or to indicate if there wish was to withdraw from the study.

Introducing the short second recruitment and follow up period ensured statistical power was preserved. There was no difference in mean body weight, BMI, waist circumference or gender between subjects who completed the HF2 study and subjects who were lost to follow up but there was a significant difference in age and SIMD category (Table 5.1).

Figure 5:1: Consort Flow Diagram for Progression through Healthforce2

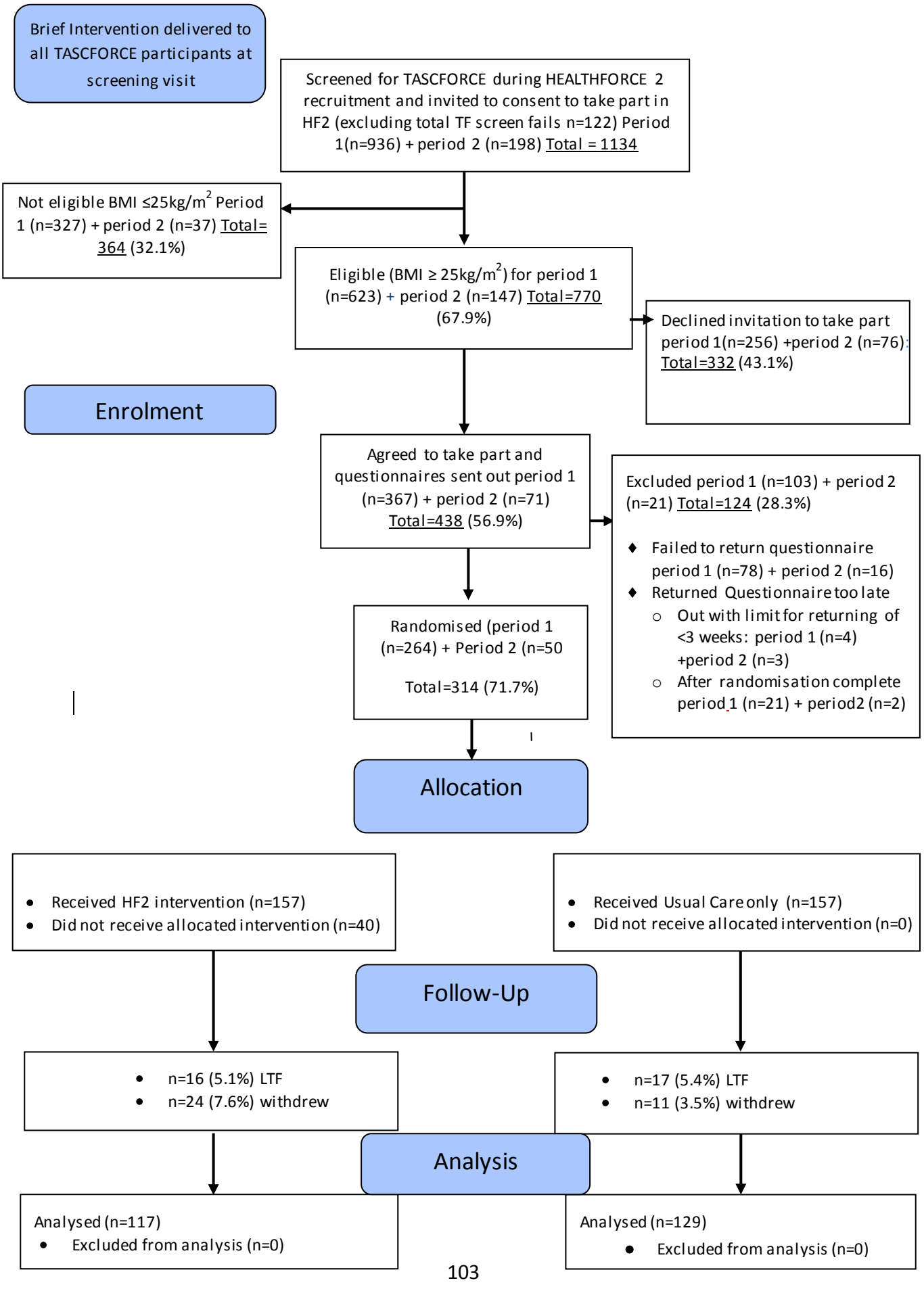

Table 5:1: Per protocol and LTFU participants, baseline body weight, BMI, Waist circumference, age, gender and SIMD. Values are Mean, SD and Range

	Per Protocol (n=246) Mean (SD) Range	LTFU (n=68) Mean (SD) Range	Difference Mean, p-value 95% (CI)
Body weight (kg)	85.3 (13.3) 57 - 141	85.8 (13.5) 61 – 120	0.48 *p=0.795 (-4.07 - 3.12)
Body mass index (Kg/m^2)	30.5 (4.3) 25.0 – 62.9	31.0 (3.6) 25.3– 41.6	0.47 *p=0.408 (-1.59 – 0.65)
Waist circumference (cm)	96.8 (9.9) 76 – 134.5	96.1 (9.9) 76.4 – 121.0	0.74 *p=0.593 (-1.99 – 3.47)
Age	53.7 (8.3) 40-75	49.8 (6.6) 40-64	3.95 *p=<0.01 (1.78 - 6.11)
	Per Protocol (n=246) Mean (SD) N (%)	LTFU (n=68) Mean (SD) N (%)	Difference p-value
Gender: Male Female	 99 (40.2) 147 (59.8)	 23 (33.8) 45 (66.2)	 *p= 0.399
Scottish Index of Multiple Deprivation: 1 (High 1-3) 2 (Medium 4 - 7) 3 (Low 8 – 10)	 60 (24.4) 90 (36.6) 96 (39.0)	 27 (39.7) 23 (33.8) 18 (26.5)	 *p=0.032

Between group difference – Mean, 95% confidence intervals and *p values

5.1.2 Representativeness of the TASCFORCE and HF2 Samples to the Scottish Health Survey Population

The TASCFORCE screening sample age range of 40 to 75 years, and mean BMI of 27.1 kg/m^2 was found to be similar to that found in the 35 to 74 year old age group of the SHS (28.3 kg/m^2) (7). A one sample t-test showed no significant difference between the SHS and the total TASFORCE mean BMI (p=0.500 (CI -8.22 – 7.02)). The

TASCFORCE study sample from which HF2 participants were recruited were considered representative of the Scottish population as a whole for overweight and obese participants (Table 5.2).

The HF2 study sample was selected to include only subjects who were overweight and obese. An Independent t test showed a significant difference between the HF2 sample and total TASCFORCE sample from which it was drawn, (mean= -3.5kg/m^2 (SE 0.25), CI (-4.15 – 2.84) p=<0.001), therefore, the mean BMI of the HF2 study participants was as expected higher than the sample from the Scottish Health Survey and the TASCFORCE sample.

Table 5:2 Scottish BMI comparisons to TASCFORCE and Healthforce2 sample

Mean BMI (kg/m^2)	Scottish Health Survey sample (2012) Age 35-74	Total TASCFORCE sample (n=4424) Age 40 – 75	Total TASCFORCE sample eligible for HF2 (BMI ≥25kg/m^2) (n=2893) Age 40 – 75	Total Healthforce2 sample (BMI ≥ 25 kg/m^2) n=314 Age 40 – 75
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
	28.3 (0.45)	27.1 (0.78)	29.5 (4.25)	30.6 (4.17)

Sample Mean and SD.

5.1.3 Baseline socio-demographic characteristics

The HF2 (ITT) sample at randomisation comprised 314 participants of which the majority were female (61.1% vs 38.9% males). Of these, 246 (78.3%) completed follow up visits (Per Protocol). The per protocol group included 99 (40.2%) males with a mean age of 51 years (SD 7.5) and 147 (59.8%) females with a mean age of 56 years (SD 8.3). Baseline characteristics for the ITT and Per Protocol sample are described in Tables 5.3 and 5.4.

Table 5:3: Intention to treat sample characteristics at randomisation. Values are numbers (%) unless stated.

Baseline Characteristics	ITT (n=314)	Intervention (n=157)	Control (n=157)	Group difference p value
Age (years) mean (SD) range	*53.0 (8.2) 40 - 75	52.9 (8.5) 40 – 75	53.0 (7.9) 40 – 74	P=0.929
Gender: n (%) • Male: • Female	 122 (38.9) 192 (61.1)	 54 (34.2) 104 (65.8)	 68 (43.6) 88 (56.4)	P=0.105
Marital Status: n (%) • Single: • Married/Co Habiting: • Widowed/Separated/Divorced: • **Missing:	 22 (7.0) 232 (73.9) 47 (15.0) 13 (4.1)	 10 (6.3) 108 (68.4) 32 (20.3) 8 (5.1)	 12 (7.7) 124 (79.5) 15 (9.6) 5 (3.2)	 *****P=0.023**
Ethnicity: n (%) • White: • Mixed • Asian/Asian British • Other • **Missing	 294 (93.6) 1 (0.3) 5 (1.6) 1 (0.3) 13 (4.1)	 149 (94.3) 0 (0) 1 (0.6) 0 (0) 8 (5.1)	 145 (92.9) 1 (0.6) 4 (2.6) 1 (0.6) 5 (3.2)	 P=0.213
Highest Educational Qualification: n (%) • Secondary School: • Other Professional/Technical Qualification • University Degree: • Post Graduate Degree Masters/PhD: • **Missing:	 98 (31.2) 149 (47.5) 32 (10.2) 16 (5.1) 19 (6.1)	 54 (34.2) 70 (44.3) 15 (9.5) 8 (5.1) 11 (7.0)	 44 (28.2) 79 (50.6) 17 (10.9) 8 (5.1) 8 (5.1)	 P=0.688
Employment Status: n (%) • Retired: • Employed Full time: • Unemployed: • Employed Part time: • Student Part-time • Other: • **Missing:	 61 (19.4) 168 (53.5) 10 (3.2) 51 (16.2) 1 (0.3) 10 (3.2) 13 (4.1)	 33 (20.9) 78 (49.4) 5 (3.2) 27 (17.1) 0 (0) 7 (4.4) 8 (5.1)	 28 (17.9) 90 (57.7) 5 (3.2) 24 (15.4) 1 (0.6) 3 (1.9) 5 (3.2)	 P=0.555
(1) Scottish Index of Multiple Deprivation: n (%) • 1 (High 1-3): • 2 (Medium 4 - 7): • 3 (Low 8 – 10):	 83 (26.4) 115 (36.6) 116 (36.9)	 50 (31.6) 52 (32.9) 56 (35.4)	 33 (21.2) 63 (40.4) 60 (38.5)	 P=0.099
(1) Seasonal Group: n= (%) • Dec/Jan/Feb • Mar/April/May • Jun/July/Aug • Sep/Oct/Nov	 50 (15.9) 37 (11.8) 78 (24.8) 149 (47.5)	 24 (15.3) 20 (12.7) 38 (24.2) 76 (48.4)	 26 (16.6) 17 (10.9) 40 (25.5) 73 (46.8)	 P=0.973

*Mean age and range **No response to question ***p=<0.05

(1) SIMD and Seasonal group are grouped deciles

Table 5:4 Per Protocol sample characteristics at randomisation. n= numbers (%)

Baseline Characteristics	Per Protocol (n=246)	Intervention (n=117)	Control (n=129)	Group difference p value
Age (years) mean (SD) range	*53.7 (8.3) 40 -75	53.9 (8.7) 40-75	53.5 (8.1) 40- 74	P=0.708
Gender: n (%) • Male: • Female	 99 (40.2) 147 (59.8)	 42 (35.6) 76 (64.4)	 57 (44.5) 71 (55.5)	P=0.153
Marital Status: n (%) • Single: • Married/Co Habiting: • Widowed/Separated/Divorced: • **Missing:	 15 (6.1) 190 (77.2) 36 (14.6) 5 (2.0)	 6 (5.1) 85 (72.0) 24 (20.3) 3 (2.5)	 9 (7.0) 105 (82.0) 12 (9.4) 2 (1.6)	***P=0.045
Ethnicity: n (%) • White: • Mixed • Asian/Asian British • Other • **Missing	 237 (96.3) 1 (0.4) 2 (0.8) 1 (0.4) 5 (2.0)	 115 (97.5) 0 (0) 0 (0) 1 (0.8) 3 (2.5)	 122 (95.3) 1 (0.8) 2 (1.6) 0 (0) 2 (1.6)	P=0.499
Highest Educational Qualification: n (%) • Secondary School: • Other Professional/Technical Qualification • University Degree: • Post Graduate Degree Masters/PhD: • **Missing:	 76 (30.9) 120 (48.8) 28 (11.4) 15 (6.1) 7 (2.8)	 40 (33.9) 54 (45.8) 14 (11.9) 7 (5.9) 3 (2.5)	 36 (28.1) 66 (51.6) 14 (10.9) 8 (6.3) 4 (3.1)	P=0.767
Employment Status: n (%) • Retired: • Employed Full time: • Student Full time: • Unemployed: • Employed Part time: • Other: • **Missing:	 55 (22.4) 132 (53.7) 0 (0) 8 (3.3) 38 (15.4) 8 (3.3) 5 (2.0)	 29 (24.6) 61 (51.7) 0 (0) 3 (2.5) 17 (14.4) 5 (4.2) 3 (2.5)	 26 (20.3) 71 (55.5) 0 (0) 5 (3.9) 21 (16.4) 3 (2.3) 2 (1.6)	P=0.779
(1) Scottish Index of Multiple Deprivation: n (%) • 1 (High 1-3): • 2 (Medium 4 - 7): • 3 (Low 8 – 10):	 60 (24.3) 90 (36.6) 96 (39.0)	 35 (29.7) 40 (33.9) 43 (36.4)	 25 (19.5) 50 (39.1) 53 (41.4)	P=0.181
(1) Seasonal Group: n= (%) • Dec/Jan/Feb • Mar/April/May • Jun/July/Aug • Sep/Oct/Nov	 42 (16.6) 31 (10.9) 54 (25.5) 119 (46.8)	 20 (17.1) 17 (14.5) 23 (19.7) 57 (48.7)	 22 (17.1) 14 (10.9) 31 (24.0) 62 (48.1)	P=0.757

*Mean age and range **No response to question ***p=<0.05

(1) SIMD and Seasonal group are grouped deciles

The randomised groups completing were well matched for age, gender, educational qualification, employment and deprivation. The majority of participants were white (96.3%), employed full time (53.7%) and had a professional or technical qualification (48.8%). Participant representation across the range of SIMD deciles was good with 39% in the three least deprived SIMD deciles (8 – 10). The only significant between group difference seen in baseline socio-demographic characteristics was in marital status, with a significantly lower proportion in the intervention group married or co-habiting and twice as many participants widowed, separated or divorced (20.3% vs. 9.4%, respectively) than the control group.

5.2 Results (2) Weight loss

The study was powered to a detect weight loss of 7%; therefore, an intention to treat analysis was carried out on the primary outcome only. Secondary outcomes were analysed using data from only those subjects who completed the study. To preserve sample size and prevent bias from a non-representative sample a multiple imputation method was used to account for missing data. The methods used to apply a multiple imputation process are reported in Appendix S.

5.2.1 Weight loss

When the data was adjusted following multiple imputation, weight loss was shown not to be statistically significant (between group difference 0.9kg, p=0.09, CI -0.14 – 1.92) (Table 5.5), however, analysis of the Per protocol data indicated that the intervention group lost significantly more weight than the control group (between group difference 1.1kg, p= 0.02, CI 0.16 – 2.06).

Table 5:5 Weight loss (kg) Per Protocol sample and Intention to treat dataset

Intention to Treat		Intervention (n=157)		Control (n=157)		Between group difference baseline to follow-up Mean (CI), p value
		Mean (SD)	Mean kg weight loss (SE)	Mean (SD)	Mean kg weight loss (SE)	
Body weight (kg)	Baseline Follow up	85.6 (12.8) 83.5 (12.6)	-2.1 (1.82) P=0.238	86.7 (14.3) 83.8 (13.2)	-2.9 (0.36) P=0.097	-0.88,(-1.91 to 0.14) P=0.090
Per Protocol		Intervention (n=117)		Control (n=129)		Between group difference baseline to follow-up Mean (CI), p value
		Mean (SD)	Mean kg weight loss (SD)	Mean (SD)	Mean kg weight loss (SD)	
Body weight (kg)	Baseline Follow up	83.8 (12.4) 81.6 (12.4)	-2.2 (3.31) **P=<0.005**	86.7 (13.9) 85.6 (13.0)	-1.1 (4.16) **P=<0.005**	-1.10 (-2.05 to -0.156) ***P= 0.023**

Mean (kg) weight loss with 95% confidence intervals: difference between randomised groups *P=<0.05

5.2.2 Controlling for baseline weight

General linear model univariate analysis applied to the primary outcome weight loss, showed, when controlling for randomised group and baseline weight the treatment effect decreased: mean weight loss for intervention group, 1.4kg, p=<0.01, (95% CI 0.44-2.36) compared to 1.1kg for control group, p=0.02 (95% CI 0.16-2.06), a difference of 0.3kg, p=<0.01, (95% CI 0.40 – 2.25,) for *per protocol* data. Using the *intention to treat* data, the intervention group lost 1.0 kg, p=0.05, (95% CI, -0.00 -1.82) compared to 0.9kg for the control group, p=0.09, (95% CI, -014 -1.92), a difference of 0.1kg, p=0.05, (95% CI, -0.31 – 1.71).

5.3 Results (3) Change in Cardiovascular Risk Factors

5.3.1 BMI and Waist Measures

Results from BMI and waist measurements are seen in Table 5.6. A significant between group difference is shown at follow up for waist measurement (-1.21cm p=0.002) but not for calculated BMI, however, the difference from baseline to follow up BMI in both groups was significant, -0.8kg/m^2 p=<0.001 in the intervention group versus -0.7 kg/m^2 p=<0.001 in the control group. A significant difference was also seen in waist measurement from baseline to follow up with a 4cm loss (p=<0.001) in the intervention group versus 2.8cm loss (p=<0.001) in the control group.

Table 5.6 Anthropometric measures per randomised group

		Intervention (n=118)		Control (n=128)		Change between groups from baseline to follow-up Mean (CI), p value
		Mean (SD)	Difference to baseline Mean (SD) P-value	Mean (SD)	Difference to baseline Mean (SD) P-value	
BMI (kg/m^2)	Baseline Follow up	30.2 (4.63) 29.4 (4.54)	-0.8 (1.14) P=<0.001	30.4 (4.11) 29.7 (4.05)	-0.7 (1.47) P=<0.001)	-0.28 (-1.521 to -0.948,) p= 0.648
Waist circumference (cm)	Baseline Follow up	95.4 (8.74) 91.4 (8.41)	-4.0 (5.10) P=<0.001	98.0 (11.24) 95.2 (9.86)	-2.8 (19.98) P=<0.001	-1.21 (-6.021 to 0.904) ***p=0.002**

BMI (kg/m^2) and Waist circumference (cm) difference between groups at follow up Mean with 95% confidence intervals *p=<0.05

5.3.2 Summary of main findings from follow up CVD risk factors

Baseline and follow up measures for cardiovascular risk factors, including systolic and diastolic blood pressure, lipid profile, non-fasting blood glucose and cardiovascular risk score (based on the Framingham risk assessment algorithm (159) are reported in Table 5.7.

5.3.2.1 Blood Pressure

Reductions in both systolic and diastolic blood pressures (mmHg) were seen in both groups, with a larger but not significant reduction in systolic BP in the intervention group. Mean diastolic reduction in the intervention group was statistically greater than in the control group: - 3.25 mmHg (SD=7.8) versus. -2.68 mmHg (SD=7.8), respectively (95% CI -4.57, -0.68 p=0.008).

5.3.2.2 Total Cholesterol

Participants from both groups significantly reduced their total cholesterol levels; however, the reduction in the intervention group was significantly greater than in the control group: -0.37 mmol/L (SD=0.7) versuss.-0.29 mmol/L (SD=0.7) respectively (95% CI -0.45 – 0.09, p=0.003).

5.3.2.3 Blood Lipids

There was no significant difference between groups when absolute mmol/L non-fasting triglyceride levels were measured. The intervention group slightly reduced levels -0.04 mmol/L) and the control group slightly increased levels (0.01 mmol-L).

Both groups increased absolute mmol/L HDL cholesterol levels, but not significantly, however, both groups reduced their LDL cholesterol levels with a significant between group mean difference of -0.22 (p=0.034).

5.3.2.4 Blood Glucose

The between group difference was non-significant for non-fasting blood glucose (p=0.426), however, the intervention group showed a small but significant reduction (p=0.046).

5.3.2.5 CVD risk score

Both groups significantly reduced calculated 10 year CVD Framingham risk scores at follow up (p=<0.001). The control group achieved the greater reduction 4.9% to 4.0% versus 4.1% to 3.3% in the intervention group although there was no between group significance.

Table 5:7 Cardiovascular risk values Per protocol sample. Independent T-tests show mean differences with 95% confidence intervals p=<0.05 *significant values

	Baseline		Follow-up		Within group change	Between group differences from baseline to follow-up
Measures	N=	Mean (SD) Range	N=	Mean (SD) Range	Mean (SD), P-value	Mean (95% CI), P value
Systolic blood pressure (mm Hg):						
Intervention	117	126.1 (11.8) 94-145	117	122.0 (10.7) 98 -144	-4.02 (8.2) P=<0.001	1.20 (-0.98-3.39), P=0.281
Control	129	126.3 (11.9) 100-145	129	122.7 (11.8) 98 -158	-3.57 (9.1) P=<0.001	
Diastolic blood pressure (mm Hg):						
Intervention	117	73.8 (10.0) 50 - 95	117	70.5 (9.4) 50 - 90	-3.25 (7.8) P=<0.001	2.63 (0.68 – 4.57), ***P=0.008**
Control	129	75.2 (10.0) 50 - 90	129	72.5 (9.9) 50 - 90	-2.68 (7.8) P=<0.001	
Total Cholesterol (mmol/L):						
Intervention	117	5.5 (0.98) 2.7-8.1	117	5.2 (0.88) 2.5-7.0	-0.37 (0.7) P=<0.001	-0.27 (-0.45 - 0.09), ***P=0.003**
Control	129	5.6 (0.90) 3.6-8.8	129	5.3 (0.87) 3.1-7.7	-0.29 (0.7) P=<0.001	
HDL Cholesterol (mmol/L):						
Intervention	117	1.2 (0.45) 0.4- 2.4	117	1.3 (0.41) 0.3-2.5	0.11 (0.3) P= 0.003	-0.01 (-0.10 - 0.06), P=0.706
Control	129	1.2 (0.47) 0.4- 2.5	127	1.3 (0.47) 0.3-3.9	0.09 (0.3) P=<0.001	
LDL Cholesterol (mmol/L:						
Intervention	111	3.51 (0.85) 0.9- 5.6	113	3.02 (0.80) 0.9-4.8	-0.49 (0.7) P=<0.001	-0.22 (-0.41 to -0.01),***P=0.034**
Control	124	3.50 (0.84) 1.7- 6.0	119	3.09 (0.79) 1.1-5.3	-0.38 (0.7) P=<0.001	
Triglycerides (mmol/L):						
Intervention	117	1.79 (1.15) 0.5-7.2	118	1.75 (0.95) 0.5- 4.8	-0.04 (0.9) P=0.646	0.9 (-0.73 - 2.53), P=0.280
Control	129	1.90 (1.12) 0.5-7.3	127	1.91 (1.13) 0.5- 6.1	0.01 (1.0) P=0.850	
Non Fasting Blood Glucose (mmol/L):						
Intervention	117	5.35 (0.76) 3.5-8.3	117	5.17 (0.77) 3.5- 7.6	-0.17 (0.9) ***P=0.046**	0.69 (1.00 - 2.38), P=0.426
Control	129	5.36 (0.80) 4.0-9.9	127	5.32 (0.83) 3.4- 9.1	-0.03 (0.9) P=0.680	
Framingham Cardiovascular Risk Score						
Intervention	117	4.1 (3.92) 0 - 16	117	3.3 (3.91) 0 - 20	-0.79 (1.9) P=<0.001	0.07 (-0.18 –0.33), P=0.185
Control	129	4.9 (4.53) 0 - 18	126	4.0 (4.12) 0 - 20	-0.86 (2.5) p=<0.001	

5.4 Results (4) Factors which influenced weight loss

5.4.1 Predictors for Weight Loss

Regression modelling was used to explore which factors may have been predictors in order to test whether a significant amount of variation in weight loss could be explained by differences in individual anthropometric or demographic characteristics. As the number of factors available to test is limited by the sample size, 10 were chosen using a p-value of 0.05 as a cut off. The variables chosen to investigate were hypothesis generated:

- Randomised Group
- Gender
- Baseline Total Cholesterol
- Baseline Body Mass Index (kg/m^2)
- Waist to hip ratio (cm)
- SIMD category (1-3 high deprivation, 4-7 medium, 8-10 low)
- Educational attainment
- Employment status
- Marital status
- Seasonal groups

As the data regarding these variable was available it was considered prudent to analyse each individually so as not to dismiss any which may have had an influence on weight loss. General linear modelling was used to test each variable independently, as it can additionally test for categorical predictors. Where variables were found to be significant predictors of weight loss ($p=<0.05$) these significant predictors were in turn entered into a two-variable model with non-significant variables being removed from the analysis. The process continued resulting in a three variable model where all variables and interactions in the model were

significant (p=<0.005). (See Appendix S for models used in the process) Table 5.8 show the variables used and significance of predictive values.

Table 5:8 Univariate independent variable models used to predict kg weight loss

Predictor Variables	P -values	Significant predictor	Adjusted R^2
Randomised Group	<0.001*	Yes	0.068
Seasonal Group	<0.005*	Yes	0.044
Gender	0.241	No	0.002
Baseline BMI Index (kg/m2)	0.064	No	0.011
Waist to Hip ratio	0.399	No	0.013
Employment	<0.001*	Yes	0.016
Marital status	<0.001*	Yes	0.064
Educational attainment	0.732	No	0.009
Baseline Total cholesterol	0.719	No	0.028
SIMD category • 1-3 high deprivation • 4-7 medium • 8-10 low	0.404	No	0.001

General Linear Modelling: *significant predictors for weight loss p=<0.05

The one variable model showed that randomised group, marital status, employment and seasonal grouping were all significant predictors for weight loss, (p<0.001, p<0.001, p<0.001 and p<0.005 respectively).

5.4.2 Marital status effects on weight loss

Marital status was a significant predictor for weight loss, p= <0.001 and an R^2 value of 0.064 indicating that it explained approximately 6.4% of the variation in weight loss. Analyses of marital status showed greatest weight loss in the widowed, separated or divorced group for both intervention and control groups (2.9kg (SD1.9

v's 2.2kg (SD 2.4)) respectively (Figure5.2). The intervention group showed greatest overall weight loss per marital status, 2.1kg (SD 0.7) versus 1.1kg (SD 0.9).

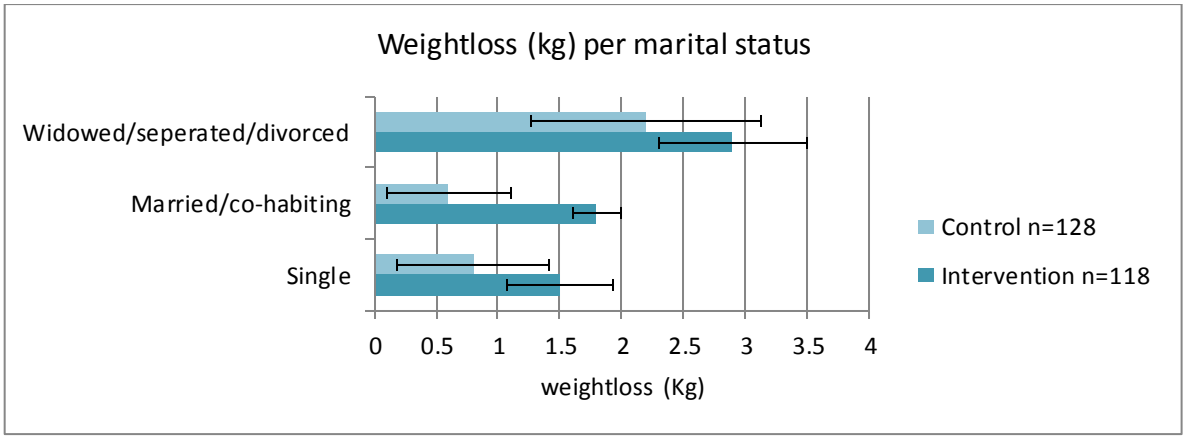

Figure 5:2 Weight loss (kg) by marital status. Error bars represent standard error of the mean.

Regression analysis, shows marital status predictor for weight loss ANOVA p=<0.001

5.4.5 Seasonal weight loss difference

Analysis of weight loss by seasonal grouping was a significant predictor for weight loss independent of marital status p=<0.005 and an R^2 value of 0.044 indicating that it explained approximately 4.4% of the variation in weight loss. Analyses of weight loss by seasonal grouping showed greatest weight loss in the December through to February cohort with the greatest weight reduction in the intervention group (2.9kg (SD1.55)), and March through to May in the control group (1.6kg (SD 2.4)). Figure 5.3 illustrates weight loss (kg) over seasonal groups with the intervention group achieving a greater mean kg weight loss (kg) across all seasonal groupings, intervention group 2.1kg (SD 0.9) versus control group 0.9kg (SD 1.0).

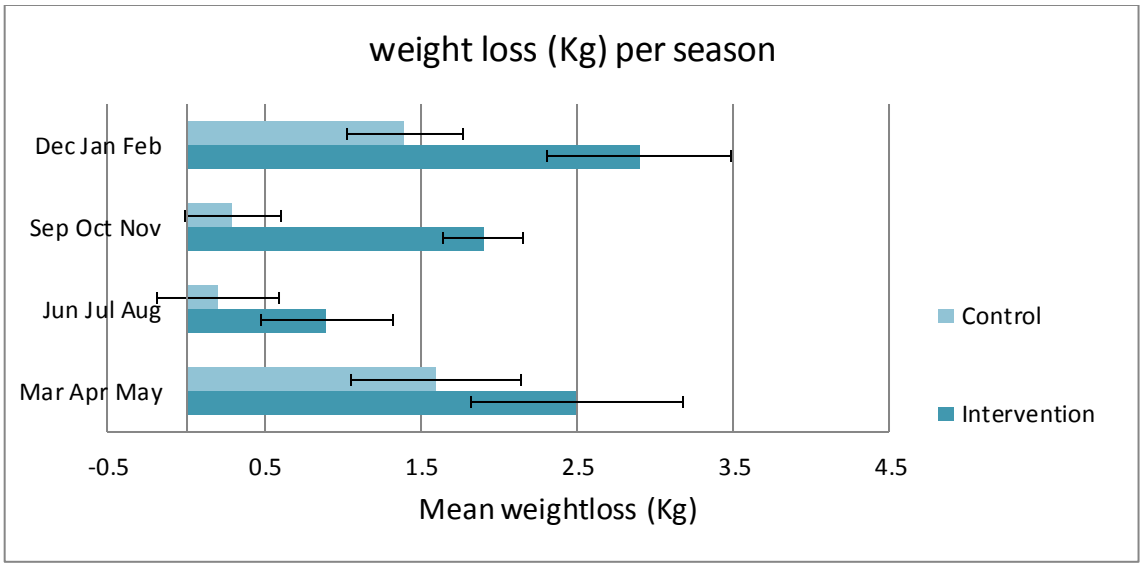

Figure 5:3 Weight loss (kg) by season. Error bars represent standard error of the mean. Regression analysis shows seasonal grouping a predictor for weight loss ANOVA p=<0.005

5.4.3 Effect of employment on Weight loss

Employment status was a predictor for weight loss p=<0.001 with an R^2 value of 0.016 indicating that it explained approximately 1.6% of the variation in weight loss. In the intervention group the greatest proportion of participants were employed full time (n=56) or in the retired group (n=26). This was also the case in the control group with participants employed full time (n=69) and retired (n=25) respectively. The greatest weight reduction in the intervention group was seen in the retired; (3.4kg,SD 2.2) and greatest weight reduction in the control group was seen in the employed part time group (2.0kg SD 2.0) (Figure 5.4) The intervention group achieved a greater mean kg weight loss across all employment groupings, intervention 2.2kg (SD 0.8) versus control 1.3kg (SD 0.7).

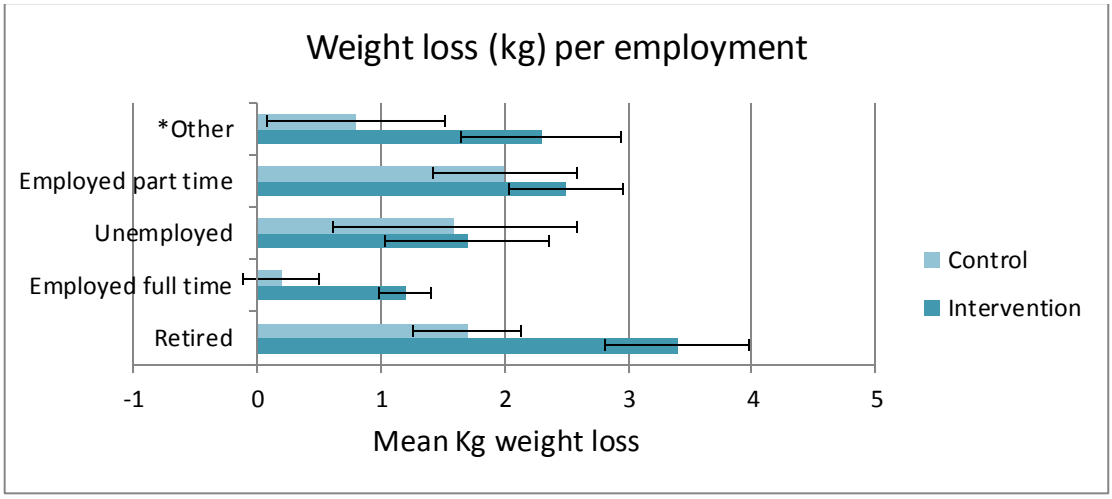

Figure 5:4 Weight loss (kg) by employment status: Error bars represent standard error of the mean. Regression analysis, ANOVA p=<0.001

* Other" full time and part time students/ self-employed

5.5 Results (5) Changes in diet and lifestyle behaviours

5.5.1 Views on Initiating Dietary Change

Questionnaires were completed to assess participant's views with regard to readiness and confidence to initiate a change in diet (Appendix I and J) and chi square tests were used to determine differences between groups. There was no significant difference between groups at baseline (p=0.131) or follow up (p=0.324) and significance was not reached in the change in their response from baseline to follow up (p=0.106).

The intervention group showed 88.7% of participants reporting they were "currently thinking about eating a healthy diet in the future" compared with 81.7% in the control group at baseline. When asked if feeling confident about "sticking to a plan to eat healthier" there was no between group difference at baseline (p=0.226) and follow up (p=0.062) and no difference in the change in their response from baseline to follow up (p=0.648).

Figure 5.5 shows the changes in levels of confidence per group from baseline to follow up. Of those who went on to make changes, as reported in the question "are you still eating a healthy diet", more participants in the control group (76%) than the intervention group (74.6%) reported continuing to eat a healthy diet, this did not demonstrate a significant change (Table 5.9).

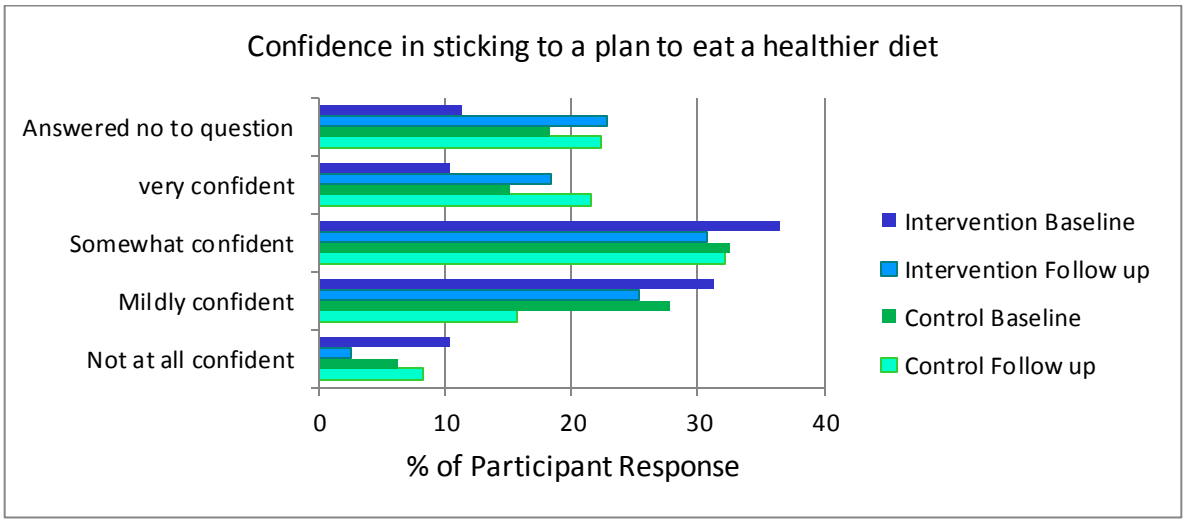

Figure 5:5 Between group difference in Participant confidence levels in sticking to plan to eat a healthier diet baseline to follow up. Values shown as % from data in table 22; p=0.648

Table 5:9 Views on initiating dietary change

	Baseline				Follow up				Between Group Difference
	Intervention n=115	(%)	Control n=126	(%)	Intervention n=114	(%)	Control n=121	(%)	
Currently thinking about eating a healthier diet in the future									
Yes	102	(88.7)	103	(81.7)	88	(77.2)	94	(77.7)	P=0.324
No	13	(11.3)	23	(18.3)	26	(22.8)	27	(22.3)	
Total	115		126		114		121		
If yes when do you plan to begin eating a healthier diet									
Within next month	88	(76.5)	85	(67.5)	76	(66.7)	81	(67.0)	P=0.615
Within next 6 months	3	(2.6)	2	(1.6)	3	(2.6)	3	(2.5)	
Yet to decide	11	(9.6)	16	(12.7)	9	(7.9)	10	(8.3)	
Answered no to question	13	(11.3)	23	(18.3)	26	(22.8)	27	(22.3)	
Total	115		126		114		121		
How confident are you that you will stick to this plan									
Very confident	12	(10.4)	19	(15.1)	21	(18.4)	26	(21.5)	P=0.648
Somewhat confident	42	(36.5)	41	(32.5)	35	(30.7)	39	(32.2)	
Mildly confident	36	(31.3)	35	(27.8)	29	(25.4)	19	(15.7)	
Not at all confident	12	(10.4)	8	(6.3)	3	(2.6)	10	(8.3)	
Answered no to question	13	(11.3)	23	(18.3)	26	(22.8)	27	(22.3)	
Total	115		126		114		121		
Have you ever made deliberate effort to improve your diet									
Yes	95	(82.6)	103	(81.7)	102	(89.5)	105	(86.8)	p=0.918
No	20	(17.4)	24	(19.0)	12	(10.5)	15	(12.4)	
Total	115		126		114		121		
If yes are you still eating a healthy diet									
Yes	64	(55.7)	81	(64.3)	85	(74.6)	92	(76.0)	P=0.307
No	31	(27.0)	22	(17.5)	17	(14.9)	14	(11.6)	
Answered no to question	20	(17.4)	24	(19.0)	12	(10.5)	15	(12.4)	
Total	115		126		114		121		
If yes have you been able to maintain eating a healthy diet									
Yes	40	(34.8)	53	(42.1)	57	(50.0)	54	(44.6)	P=0.470
No	24	(20.9)	28	(22.2)	28	(24.6)	38	(31.4)	
Answered no to question	20	(17.4)	24	(19.0)	12	(10.5)	15	(12.4)	
Did not answer the question	31	(27.0)	21	(16.7)	17	(14.9)	14	(11.6)	
Total	115		126		114		121		

Questionnaire not completed at baseline Group 1 n=2 / Group 2 n=3

Questionnaire not completed at follow up Group 1 n=3/ Group 2 n=8

Values numbers and percentage with between group differences at follow up

5.5.2 Reported dietary intake

5.5.2.1 Total Fat /unsaturated fat Scores

Results from the DINE questionnaire administered to subjects pre and post intervention provided a score indicating the level of consumption of foods high in total and unsaturated fat. The results are shown in Table 20. Both groups' total fat scores were in the low category a score less than 30 which represent a fat intake of 83g per day or less corresponding to 35% of the energy RDA for an average woman (168).

Independent t tests showed both groups significantly reduced their fat intake: intervention group by 5.1 (SD 9.4) and control group by 3.7 (SD 8.5), however, the degree of change was not significantly different between the groups.

Unsaturated fat intake scores increased in the intervention group from 8.5 (SD 1.7) to 8.7 (SD 2.3) however the control group decreased from 8.8 (SD 2.0) to 8.5 (SD 2.1). Neither groups change was significant nor was there significant difference between groups (mean score difference 0.24, p=0.413, 95% CI -0.34-0.82).

5.5.2.2 Fruit, vegetable and fibre intake

At baseline both groups fibre intake was low, less than 30 which corresponds to a fibre intake of 20g/day or less. Whereas the intervention group increased their fibre score significantly from 27.4 (SD 10.5) to 30.5 (SD 9.8), and out of the low category the control group reduced their intake from 28.1 (SD 9.4) to 26.6 (SD 10.3). This change in intake between the groups was significantly different 4.11 p=0.003, (95% CI 1.417-6.802).

Both groups significantly increased total number of fruit and vegetable portions over a 24hr period. Table 5.10 shows between group differences in change in number of portions consumed at follow up not to be significant. Both groups level of fruit and vegetable intake was high, possible reasons for why this may be are reviewed in the discussions chapter (section 6.7.2.3).

Table 5:10 Baseline and follow up changes from the DINE (163) and Facet (164) dietary questionnaire data

	N=	Intervention Mean (SD)	N=	Control Mean (SD)	Between group difference from baseline to follow-up: mean, CI and P value
Total Fat score					
Baseline Follow up Difference to baseline	117 112	25.3 (10.7) 20.1 (7.2) -5.1 (9.4) P=<0.001	129 120	24.9 (9.9) 21.2 (8.9) -3.7 (8.5) P=<0.001	-1.06 (-3.14 – 1.02) p=0.318
Total Unsaturated Fat score					
Baseline Follow-up Difference to baseline	117 112	8.5 (1.7) 8.7 (2.3) -0.2 (2.4) P=0.254	129 120	8.8 (2.0) 8.5 (2.1) 0.4 (2.6) P=0.112	0.24 (-0.33 – 0.82) P=0.413
Total Fibre score					
Baseline Follow-up Difference to baseline	117 112	27.4 (10.5) 30.5 (9.8) 2.7 (10.1) P=<0.001	129 120	28.1 (9.4) 26.6 (10.3) -1.3 (10.7) P=0.001	4.11 (1.41 – 6.80) **P=**0.003**
Number of fruit and vegetable portions in 24 hours					
Baseline Follow-up Difference to baseline	115 128	*5.3 (3.1) 6.6 (3.6) 1.4 (4.0) P=0.004	114 124	5.5 (3.1) 6.8 (3.2) 1.3 (3.1) P=0.002	-0.109 (-1.07-0.85) P=0.825

Values are mean total scores, *number of daily portions of fruit and vegetables. Last column mean difference from baseline to follow up between groups, with confidence intervals and level of significance**p=<0.05

5.5.2.3 Sugar Intake

Both groups reported similar numbers of sugar drinks consumed at baseline, with no significant difference per group from baseline to follow up. A Pearson Chi square test also indicated no association between group allocation and change in number of sugary drinks consumed at follow up (p=0.737). Change in number of teaspoons of sugar consumed per day also showed no significant difference between groups mean 0.4, (95% CI-0.86 – 0.11) p=0.793, however, the intervention group did show a significant reduction from baseline to follow up from 1.0 to 0.5 of a spoonful, p=0.029 (Table 5.11).

Table 5.11 Reported sugar intake

Average number of *sugar drinks	Intervention N=117 Mean (SD)	Control N=124 Mean (SD)	Between group Difference P value
Baseline	7.7 (1.8)	7.7 (1.6)	
Follow up	7.6 (2.0)	8.0 (1.6)	p=0.737
Difference to baseline	P=0.233	P=0.450	
Average number of spoonful's of sugar daily			Between group mean Difference, 95% CI and P value
Baseline	1.0 (0.26)	0.7 (0.17)	0.4 (-0.86 – 0.11)
Follow up	0.5 (0.15)	0.9 (0.22)	p=0.134
Difference to baseline	P=0.029	P=0.528	
Change in average number of sugar drinks	N=111 N (%)	N=117 N (%)	
Increased	29 (26.1)	33 (28.2)	
Decreased	18 (16.2)	19 (16.2)	p=0.935
No Change	64 (57.7)	65 (55.6)	
Change in average number of spoonful's of sugar daily	N=112 N (%)	N=117 N (%)	
Increased	13 (11.6)	12 (10.3)	
Decreased	12 (10.7)	10 (8.5)	p=0.793
No Change	87 (77.7)	95 (81.2)	

*Sugary drinks not including diet or low-calorie drinks or fresh fruit juice

5.5.2.4 Alcohol Intake

The control group had a larger number of participants never having taken alcohol than the intervention group at baseline 10.3% versus 6.8%, although not significantly. Chi Square tests were carried out on baseline and follow up measures for alcohol intake. Between group differences for frequency of drinking alcoholic drinks and reported changes in alcohol intake are shown in table 5.12 and table 5.13. At follow up the intervention group reduced drinking whilst the control group remained the same. Of those reporting drinking alcohol at follow up the control group had reduced daily intake while the intervention group remained the same. There were no significant changes shown in frequency or quantity of alcohol drunk.

5.5.2.5 Smoking

There was no difference in smoking status between groups at baseline, p=0.858. Of the nine smokers in each group one participant per group had stopped smoking at follow up (Table 5.13).

Table 5.12 Between group changes in Alcohol intake

	Baseline			**Follow-up**		
How often do you have a drink containing alcohol	Intervention (n=118) N (%)	Control (n=126) N (%)	Difference p=	Intervention (n=110) N (%)	Control (n=118) N (%)	Difference p=
Never	8 (6.8)	13 (10.3)		9 (8.2)	8 (6.8)	
Monthly or less	24 (20.4)	25 (19.8)		27 (24.5)	29 (24.6)	
2-4 times month	25 (21.2)	31 (24.6)	P=0.438	22 (20.0)	32 (27.1)	P=0.301
2-3 times a week	43 (36.4)	33 (26.2)		42 (38.2)	32 (27.1)	
4 or more times a week	18 (15.3)	24 (19.0)		10 (9.1)	17 (14.4)	
Alcohol intake drinks/day when drinking	Intervention (n=116) N (%)	Control (n=124) N (%)	Difference p=	Intervention (n=108) N (%)	Control (n=117) N (%)	Difference p=
N/A	8 (6.9)	13 (10.5)		8 (7.4)	8 (3.1)	
1 or 2	58 (50.0)	52 (41.9)		57 (52.8)	54 (46.2)	
3 or 4	29 (25.0)	26 (21.0)	P=0.206	29 (26.9)	28 (23.9)	p=0.245
5 or 6	13 (11.2)	22 (17.7)		11 (10.2)	14 (12.0)	
7 to 9	6 (5.2)	11 (8.9)		3 (2.8)	11 (9.4)	
10 or more	2 (1.7)	0 (0.0)		0 (0)	2 (1.7)	

Values are numbers and percentage and between group difference significance

Table 5.13 Change in alcohol consumption and smoking at follow up

Reduction in alcohol intake days/week	Intervention (n=111) n (%)	Control (n=116) n (%)	Between group difference p value
No	14 (12.6)	7 (6.0)	
Yes	22 (19.8)	30 (25.9)	
No change	75 (67.6)	79 (68.1)	P=0.169
Reduction in alcohol drinks/day	(n=105) n (%)	(n=113) n (%)	
No	37 (35.2)	38 (33.6)	
Yes	29 (27.6)	37 (32.7)	
No change	39 (37.2)	38 (33.6)	P=0.703
Smoking status	(n=118) n (%)	(n=128) n (%)	
Smoking at baseline			
Yes	9 (7.6)	9 (7.0)	
*No	109 (92.4)	119 (93.0)	
Stopped Smoking			P= 1.000
Yes	1 (0.8)	1 (0.8)	
N/A	108 (92.4)	119 (93.0)	

Values are numbers and percentage with between group differences

* combined never and ex-smokers

5.6 Results (6) from Physical Activity Questionnaires

5.6.1 Views on Initiating Physical Activity Change

Questionnaires were completed to assess participant's views with regard to readiness and confidence in increasing levels of physical activity, results are shown in table 5.14. When asked "are you currently thinking about increasing physical activity that you do?" the majority of participants at baseline and follow-up reported 'yes', 79.3% in the intervention group and 74.2% in the control group at baseline and 70.2% in the intervention group and 72.3 % in the control group at follow up. Chi square tests

showed there was no significant difference between groups at baseline or follow up (p=0.324 and p=0.131 respectively).

When asked "How confident are you that you will stick to this plan?" at baseline 63.8% in the intervention group and 54% in the control group reported to feel "somewhat" or "mildly confident" at follow up confidence had fallen in both groups to 50% in the intervention group and 52.9% in the control group with no significant between group difference p= 0.746.

At follow up a total of 38 (15.4%) participants felt very confident in increasing their physical activity 22 (19.3%) in the intervention group and 16 (13.4%) in the control group showing a significant between group difference p=0.008. Overall the majority of participants in both groups reported readiness to increase physical activity at baseline and follow up, with more people in the intervention group demonstrating an increasing confidence in doing so.

When asked at follow up "Are you still doing more physical activity? of all participants completing the programme significantly more people in the intervention group said "yes" 70.2% versus 45.4% in the control group p=<0.001.

Table 5.14 Views on changing levels of PA

	Baseline N (%)				Follow up N (%)			
	Intervention		Control		Intervention		Control	
Currently thinking of increasing amount of PA								
Yes	92	(79.3)	92	(74.2)	80	(70.2)	86	(72.3)
No	24	(20.7)	32	(25.8)	34	(29.8)	33	(27.7)
Total	116		124		114		119	
If yes when do you plan to begin doing more PA								
Within next month	77	(65.3)	72	(58.0)	70	(61.4)	68	(57.1)
Within next 6 months	6	(5.1)	7	(5.6)	4	(3.5)	7	(5.9)
Yet to decide	9	(6.8)	13	(10.5)	6	(5.3)	11	(9.2)
Answered no to the question	24	(19.5)	32	(25.8)	34	(29.8)	33	(27.7)
Total	116		124		114		119	
How confident that you will stick to this plan								
Very confident	10	(8.6)	18	(14.5)	22	(19.3)	16	(13.4)
Somewhat confident	45	(38.8)	32	(25.8)	46	(40.4)	36	(30.3)
Mildly confident	29	(25.0)	35	(28.2)	11	(9.6)	27	(22.7)
Not at all confident	8	(6.9)	7	(5.6)	1	(0.9)	7	(5.9)
Answered no to the question	24	(20.7)	32	(25.8)	34	(29.8)	33	(27.7)
Total	116		124		114		119	
Have you ever made deliberate effort to increase PA								
Yes	93	(80.2)	100	(80.6)	99	(86.8)	98	(82.4)
No	23	(19.8)	24	(19.4)	15	(13.2)	21	(17.6)
Total	116		124		114		119	
If yes are you still doing more PA								
Yes	48	(41.4)	41	(33.1)	80	(70.2)	54	(45.4)
No	45	(38.9)	59	(47.6)	19	(16.7)	44	(37.0)
Answered no to the question	23	(19.8)	24	(19.4)	15	(13.2)	21	(17.6)
Total	116		124		114		119	
If yes have you been able to maintain this increased amount of PA for 6 months or more								
Yes	31	(26.7)	26	(21.0)	46	(40.4)	33	(27.7)
No	17	(14.7)	9	(7.3)	33	(29.0)	18	(15.1)

Answered no to the question	23	(19.8)	24	(19.4)	15	(13.2)	21	(17.6)
Did not answer the question	21	(18.1)	65	(52.4)	20	(17.5)	47	(39.5)
Total	116		124		114		119	

Questionnaire not completed at baseline Group 1 n=1 / Group 2 n=5

Questionnaire not completed at follow up Group 1 n=3/ Group 2 n=1

5.6.2 Number of days per week of vigorous physical activity

Both groups were similar in reporting number of days per week physical activity. At baseline 47 participants in the intervention group (40.2%) and 44 in the control group (34.1%) reported not taking any vigorous activity at baseline. At follow up the number of participants in the intervention group reporting no vigorous activity dropped by 6% to 40 (34.2%) but increased by 1.6 % in the control group to 46 (35.7%). Pearson chi square tests confirmed there were no significant differences between randomised groups in number of days per week of vigorous activity at baseline or follow up.

There was no difference between groups at baseline p=0.966 or follow up p=0.884 in the number of minutes per week vigorous activity taken, and no change per group between baseline and follow up (intervention group: p=0.676 and control group: p=0.720).

5.6.3 Participants achieving recommended level of moderate physical activity per week

At baseline 36 participants in the intervention group (31%) and 43 in the control group (33.3%) reported no moderate physical activity, at follow up the number of participants reporting no moderate activity in the intervention group had reduced by 7.9% to 27 (23.1%). This increase in activity in the intervention group, however, was not significant.

The number of participants reported achieving 150 minutes of moderate physical activity at baseline was 35 in the intervention group (30.2%) and 22 in the control group (17.4%) At follow up 36 (31.6%) in the intervention group and 27 (22.7%) in the control group reported achieving 150 minutes per week. The percentage of participants achieving the recommended moderate level of physical activity is shown in Figure 5.6.

Overall between baseline and follow-up the percentage of participants achieving the recommended 150 minutes of moderate intensity activity per week increased for both intervention group (30.2% to 31.6%) p=0.493 and control group (from 17.4% to 22.7%) p=0.866 with the control group achieving the greater increase, this was however not a significant between group difference. Both groups increased the number of minutes per week of moderate activity but not significantly. There was no significant between group change shown at follow up p=0.572.

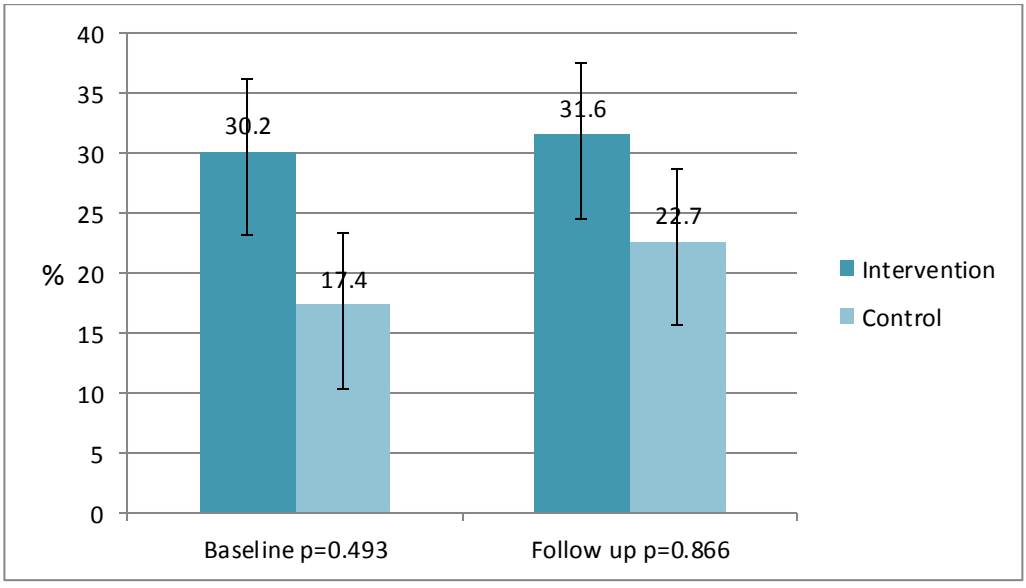

Figure 5.6 Percentage achieving recommended levels of moderate activity per week by group, baseline to follow up and levels of significance. Error bars show mean and standard error.

5.6.4 Walking

A small percentage of participants (6.1%), recalled having no walking activity at baseline in the past 7 days: (Intervention group (1.6%) and Control group (4.5%)), defined as "at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure".

At follow up all of the participants reported some walking activity. At baseline 14% (intervention group (16.3%) and control group (12.6%)) did report to some walking. This increased to a total of 31.4% at follow up: intervention group (15.4%) and control group (16%), although this was not an overall significant increase p=0.305.

5.6.5 Sedentary behaviour

Participants were asked to report time spent sitting during the previous 7 days in relation to time spent at home, work, leisure time, and including activities such as reading, visiting friends and watching television. There was no significant difference between groups on reported hours per day spent sitting at baseline; 7.1hrs (SD 3.5) in the intervention group versus 6.8hrs (SD 2.7) in the control group (p=0.060), and no significant difference at follow up p=0.283. Both groups did reduce the amount of time sitting with the intervention group achieving largest reduction from 7.1hours (SD4.6) to 5.7 hours (SD2.7) a significant mean difference from baseline to follow up of -1.4 hours (SD4.3) p=0.012.

5.7 Results (7) Cardiovascular risk perceptions

5.7.1 CVD Risk Perception

To assess participant cardiovascular risk perceptions, a questionnaire was given to all subjects' before and after the TASCFORCE screening and discussion (usual care) (see appendix H). Pearson Chi square tests were applied to the data, the results concluded there was no difference between the groups in terms of the extent to which they changed their risk perceptions pre and post screening see table 25 (p= 0.213). There was, however, a small but significant difference in the change in risk perception outcome between gender (p= 0.001), with males more likely to report an increase in perceived risk of developing CVD following the post screening "usual care" discussion (table 5.16).

Table 5.17 also shows following screening (TF brief intervention) a significant difference in median group scores for perceived CVD risk in the intervention group p=<0.001 but not the control group p=0.207 and no between group difference p=0.097. Both male and female showed a change in risk perception from average to lower than average risk but this was only significant for females p=<0.001 (males p=0.760), between gender difference was also significant for changes in perceived risk, with females perceiving less risk (p=0.010) (Table 5.16).

Table 5.15 Per protocol pre-post CVD risk perception

Pre risk perception	Total Intervention (n=118)		Total Control (n=127)		Between group difference
	n=	%	n=	%	
Much lower than average	10	(8.5)	7	(5.5)	P=0.309
Lower than average	32	(27.1)	28	(22.0)	
Average	48	(40.1)	69	(54.3)	
Higher than average	25	(21.2)	20	(15.7)	
Much higher than average	3	(2.5)	3	(2.4)	
*Pre v post risk perception questionnaire	(n=108)		(n=121)		Between group difference
	n=	%	n=	%	
Risk perception score increased	19	(17.6)	31	(25.6)	P=0.213
Risk perception score decreased	46	(42.6)	53	(43.8)	
No change in risk perception	43	(39.8)	37	(30.6)	

* Risk score not available at both time points n=17

Values are numbers and percentages with between group levels of significance

Table 5.16 Change in CVD risk perception scores by gender (pre v post TASCFORCE screening having received usual care)

	Male n=93		Female n=136		Between group difference
Pre v post risk questionnaire	n=	%	n=	%	
Risk score increased	32	34.4	18	13.2	P= 0.001
Risk score decreased	33	35.5	66	48.5	
No change in risk	28	30.1	52	38.2	
Median CVD risk perception scores	Male *n=99 **n=93 Median (IQR)	Difference to baseline	Female *n=146 **n=136 Median (IQR)	Difference to baseline	Between group difference
*Pre screening **Post screening	3 (2) 3 (2)	P=0.760	3 (2) 2 (2)	P=<0.001	^P=0.010

Risk score not available at both time points n=17.

Values are numbers and percentages, median risk scores and IQR with between group levels of significance. ^Kruscal Wallis post-hoc test for significance

Table 5.17 Median CVD risk perception scores (pre v post Tascforce screening having received usual care)

Median CVD risk perception scores	Intervention n=117 n=129 Median (IQR)	Difference to baseline	Control n=117 n=126 Median (IQR)	Difference to baseline	Between group difference
Pre-screening Post screening	3 (1) 2 (1)	P=<0.001	3 (1) 3 (2)	P=0.207	^P=0.097

Median scores per group with IQR and between group levels of significance. Scores range from 1=much lower risk to 5=much higher risk.

^Kruscal Wallis post-hoc test for significance.

5.8 Results (8) Self-Reported Quality of Life Outcomes

5.8.1 Summary Results from Quality of Life Questionnaire

The SF12v2 Quality of Life questionnaire was used to measure participants' reported health status. The questionnaire was administered at baseline and follow up. Two hundred and forty six questionnaires were included in the sample at baseline: 117 in the intervention group and 129 in the control group (37% male, 63% female), and 242 at follow up: 118 in the intervention group and 124 in the control group (40% male, 60% female). Responses from the 12 questions are combined in two summary scores; The Physical Component Summary (PCS) and The Mental Component Summary (MCS).

Table 5.18 shows HF2 group mean scores for each of the domains in the SF12v2 questionnaire which can be compared to the *"norm population" scores where each domain has a mean score of 50 and a standard deviation of 10. Independent t- tests showed there was no significant difference in mean scores between the intervention and control groups through each of the domains at baseline or follow up, however, there were significant differences seen at individual domain levels (section 5.8.2). Independent paired tests also showed significant differences in groups from baseline to follow-up (Table 5.18).

5.8.2 Changes in Reported General Health

Increases in state of general health perception were reported in table 5.18. The intervention group demonstrated a significant increase in score for vitality from

baseline to follow up of 2.1 (SD10.2). The control group reported increases of general health perception in 3 of the 8 domains and a significant decrease of 1.7 (SD9.9) in the domain of physical functioning. However, these were the only significant domain changes for either group. Both groups increased their mental health component summary scores, however, not significantly. As the study was powered to detect change in body weight the number of subjects in this sample may not have sufficient statistical power to detect changes throughout all the domains. As with the mental component summary, the physical component summary showed no significant change see table 5.18. The SF12v2 also shows a percentage of the norm and HF2 sample at risk of depression. Baseline and follow up values showed the norm population to have a 20% risk; the HF2 sample risk was lower at 15% baseline and 14% at follow up.

Table 5.18 Baseline and follow up scores from SF12V2

Scales	N=	Intervention Mean (SD)	N=	Control Mean (SD)	Between group differences: mean, CI and P value
Physical Functioning BL FU Change from baseline	 115 117	 52.8 (8.0) 52.7 (8.1) P=0.82	 126 123	 53.4 (6.9) 51.7 (8.1) **P=0.05	 0.9, (-1.11 – 3.00) P=0.36
Role Physical BL FU Change from baseline	 115 116	 53.6 (6.7) 53.3 (7.5) P=0.76	 126 122	 53.7 (6.2) 53.1 (7.5) P=0.41	 0.2, (-1.60 – 2.19) P=0.75
Bodily Pain BL FU Change from baseline	 116 116	 52.4 (8.2) 53.1 (8.3) P=0.29	 126 124	 52.0 (8.1) 51.0 (9.0) P=0.21	 2.1, (-0.09 – 4.29) P=0.06
General Health BL FU Change from baseline	 113 116	 51.8 (7.6) 53.5 (6.3) P=0.36	 127 122	 52.4 (7.1) 52.5 (7.3) P=0.45	 0.9, (-0.79 – 0.69) P=0.28
Vitality BL	 116	 52.5 (7.9)	 124	 51.9 (8.5)	 1.3, (-0.73 – 3.23)

FU Change from baseline	118	54.3 (7.2) ****P=0.02**	123	53.1 (8.3) P=0.41	P=0.21
Social Functioning BL FU Change from baseline	116 117	51.8 (7.2) 53.1 (7.3) P=0.79	125 123	52.9 (7.3) 52.8 (7.3) P=0.41	0.3, (-1.54 – 2.18) P=0.73
Role Emotional BL FU Change from baseline	115 117	50.7 (8.9) 51.7 (8.3) P=0.63	126 122	52.1 (7.4) 50.7 (9.4) P=0.34	0.9, (-1.28 – 3.24) P=0.39
Mental Health BL FU Change from baseline	116 118	51.2 (8.4) 52.4 (8.3) P=0.41	125 124	50.7 (8.9) 51.7 (8.4) P=0.24	0.7, (-1.39 – 2.83) P=0.50
Summaries					
Physical Component Summary BL FU Change from baseline	115 117	53.3 (7.5) 53.4 (6.7) P=0.94	124 122	53.5 (6.7) 52.3 (8.2) P=0.14	1.1, (-0.80 – 3.01) P=0.25
Mental Component Summary BL FU Change from baseline	115 117	50.4 (9.1) 52.2 (8.7) **P**=0.35	124 122	50.8 (8.7) 51.6 (9.3) P=0.30	0.5, (-1.70 - 2.89) P=0.60

Independent T-Test analysis. Values are scores and (SD) **P=<0.05

*SF-36v2™ Health Survey 1998 U.S. general population norms and to norm-based scoring (NBS)

The generic SF12v2 was chosen in order to analyse participant's perception pre and post intervention and demonstrate if weight reduction had an effect on, among other parameters, general health, vitality and mental health. Both groups scored higher than the norm population through all domains with the intervention group showing a greater increase in all of these domains, vitality being a significant change p=0.02.

5.9 Results (9) Participant Acceptability

5.9.1 Participant Satisfaction with the intervention

A review of the data showed overall participant satisfaction to be high. There were 80.1% of questionnaires returned and a high percentage of participants rated the HEALTHFORCE 2 study as a worthwhile or excellent program. This was significantly higher in the intervention group (94.5%) than the control group (93.9%) which is likely to be due to the differences in the "excellent" rating (between group difference p=0.046). Both groups reported the study as being useful (94.9%), helping them to change their diet (88.3%) and levels of physical activity (72.6%).

Table 5.19 Results from Participant Acceptability Questionnaire. Chi square tests for significance, p=<0.05

Questionnaire Characteristics	Intervention n= 128		Control n= 65		Group not Specified * n= 7	
	N	%	N	%		%
How did you rate the Healthforce Study?						
Waste of time	0	0.0	0	0.0	0	0.0
Disappointing	2	1.6	0	0.0	0	0.0
Fair	5	3.9	4	6.2	0	0.0
Worthwhile	69	53.9	46	70.8	7	100.0
Excellent	52	40.6	15	23.1	0	0.0
Received sufficient study information						
Not enough information	0	0.0	1	1.5	0	0.0
Sufficient information	114	89.1	61	3.8	7	100.0
More information than necessary	14	0.9	3	4.6	0	0.0
Sufficient opportunity to ask questions						
No opportunity	0	0.0	0	0.0	0	0.0
Would have liked more opportunity	1	0.8	5	7.7	2	28.6
Yes, plenty of opportunity	127	99.2	60	92.3	5	71.4
Questions answered satisfactorily						
Not at all	0	0.0	0	0.0	0	0.0
Not really	0	0.0	1	1.5	0	0.0
Reasonably	2	1.6	2	3.1	0	0.0
Satisfactorily	43	33.6	20	30.8	2	28.6
Yes, completely	83	64.8	42	64.6	5	71.4
How did you find the length of the						

questionnaires						
Too short	0	0.0	0	0.0	2	28.6
Just right	107	83.6	49	75.4	5	71.4
Too long	14	10.9	12	18.5	0	0.0
Not sure	7	5.5	4	6.2	0	0.0
How difficult did you find the questionnaires to complete						
Very Difficult	0	0.0	0	0.0	0	0.0
Quite difficult	0	0.0	0	0.0	0	0.0
Had some difficulties	22	17.2	15	23.1	3	42.9
Not difficult at all	105	82.0	49	75.4	4	57.1
Did not answer question	1	0.8	1	1.5		
Did you find taking part in the study useful						
Yes	126	98.4	61	93.8	2	28.6
No	1	0.8	3	4.6	0	0.0
Did not answer question	1	0.8	1	1.5	5	71.4
Did taking part in the study help to change Diet						
Yes	120	93.8	54	83.1	3	42.9
No	7	5.5	10	15.4	0	0.0
Did not answer question	1	0.8	1	1.5	4	57.1
Did taking part in the study help to change PA						
Yes	96	75.0	47	72.3	2	28.6
No	32	25.0	18	27.7	2	28.6
Did not answer question	0	0.0	0	0.0	3	42.9
Did Telephone calls help to change Diet/PA						
Yes	109	55.3				
No	19	9.6				
N/a	62	31.5				
Did not answer question						
Would you recommend the study to family/friends						
Yes	117	91.4	62	65.4		
No	1	0.8	0	0.0		
Unsure	3	2.3	1	1.5		
Did not answer question	7	5.5	2	3.1		

* Unable to identify which group participants were in. Did not tick box asking "Did telephone calls and posted materials help make changes to diet and/or levels of exercise" or indicate "N/A".

6. DISCUSSION

6.1 I*ntroduction*

This investigation set out to test the hypothesis that there was no difference between a multiple, contact lifestyle change intervention (HF2) versus a single brief lifestyle change intervention (usual care) on weight loss and change in cardio-vascular risk factors in volunteers from the TASCFORCE screening study. The primary outcome was body weight change at 16 weeks.

A review of the literature showed there is evidence that opportunities for initiating brief interventions or "teachable moments" in an attempt to modify unhealthy lifestyle choices are often missed by healthcare providers (section 3.5.1.7). The HF2 investigation was designed to compare the impact of the brief single contact lifestyle discussion (usual care) with a multiple contact lifestyle intervention to determine what level of intervention input would affect initiation and maintenance of change in body weight and cardio-vascular risk factors. This section will propose and discuss some of the reasons why the study outcomes may have been realised whilst others were not, and will shape further discussion within the context of currently available literature, theory and practice.

6.2 *The Sample*

The randomised HF2 intervention and control groups were well matched for age, gender, educational qualification, employment and SIMD deciles (section 5.1.2).The only significant between group difference was seen in baseline socio-demographic characteristics was in marital status, with a significantly lower proportion in the intervention group married or co-habiting and twice as many participants widowed,

separated or divorced, therefore, there were a higher proportion of participants in the intervention group living alone, suggesting that social support was given by friends and family rather than spouse or partner and contributes to the greater weight loss seen in the intervention group.

The HF2 study sample was shown to be demographically representative of the TF population and the Tayside area from which it was drawn. The total TF mean age of 53 years (58.8% female and 38% male) versus the total HF2 sample mean age of 54 years (59.8% female and 40.2% male). The HF2 study attracted almost 25% (24.3%) volunteer participants from the highest deprivation category, which are often an under recruited group, possibly as a result of the diversity in recruitment sites.

One plausible reason for successful recruitment to HF2 may be that following completion of initial CVD risk screening and participants being identified as overweight or obese the chance to receive one to one consultation with a health professional and make lifestyle modifications may be seen as an opportunity to initiate change. Studies have shown the more salient the person finds a condition relating to a research study, in this case being overweight, the more they are likely to take part (174).

Current evidence has found recruiting to studies may be slow or more of a challenge than anticipated, and can be particularly difficult to recruit from lower income populations (175), with engagement in studies favouring the affluent, and better educated (174). The Tascforce (TF) project not only recruited to target but similarly to HF2, included a substantial proportion of participants (18.7% in SIMD deciles 1-3) in the higher deprivation category.

Recruitment strategies were designed to capture a proportion of people from areas of higher deprivation. This was achieved by targeting General practices from within these areas in addition to Tesco and Stagecoach transport (bus drivers) employees. These strategies have implications for future study design to create strong recruitment strategies when targeting a particular cohort of participants. HF2 successfully recruiting a substantial number of participants from the lower SIMD deciles, where weight status and the health risks in this group are known to be greater.

6.3 *Attrition Rates*

Of the eligible participants for the HF2 study, 56.9% agreed to take part v's 43.1% who declined. At 16 weeks the intervention group had 25.5 % (40/157) participants withdraw or considered to be loss to follow up (LTFU) versus 17.8% (28/157) for the control group. While it is important to strive to have 100 % follow up in the study population it is often an unachievable goal. There will always be a proportion of research study participants who will withdraw or be lost to follow up. What is important is that those who do so are acknowledged and the reasons why explored. In both groups retention rates were more than 70% which would be considered acceptable best evidence for inclusion as effective behavioural interventions (176).

The Centers for Disease Control and Prevention's strategic plan 2010, adopted a cutoff point to meet the requirements for inclusion as best-evidence for "effective behavioral interventions" to be those that include 70% or greater retention rates in each study arm at follow up and 60% or greater retention to qualify for "promising interventions"(176). Attrition rates of greater than 30% or 40% in either study arm

are considered indicative of "fatal" flaws in the study, in effect negating intervention outcome results regardless of other qualification (177). The National Registry of Effective Prevention Programs' study quality assessment scale rates attrition most favorably handled in a given study if rates are less than 20% (178), the 20% cut off was also adopted in work aiming to synthesize intervention literature (179).

Loss to follow up is seldom considered to be strictly random, to show transparency the flow of participants through the study is shown in Figure 7 with a detailed description in section 5.1.1 describing where participants withdrew or were LTFU. While the reasons for 10% of the 68 participants not completing the study (5% in group 1 and 5% in group 2) LTFU are unknown, 30% of those 68 gave reasons for withdrawing from the study as work or family commitments, and family or personal illness.

Statistical analysis showed there was no significant difference in baseline characteristics between those who completed and those who did not. In the HF2 study attrition rates did not result in a loss of power which could have had an effect on the ability to draw robust conclusions from the study population which in turn could affect the generalisability of the study.

In terms of social deprivation there was no statistical significant difference shown in SIMD groups and decision to withdraw or loss to follow up, unusually the highest proportion of participants (39.7%) who did so were from the lowest deprivation category (SIMD 8-10) compared with 26.5% in the higher category (SIMD 1-3). There were more in the intervention group (40) than the control group (28) lost to follow up or who withdrew but this was not shown to be significant. One plausible explanation for this could be the time required for the telephone consultations with

the counsellors, as although call times were mutually agreed on the actual day other commitments may take priority and rather than call and cancel it may seem easier not to respond.

There were twice as many in the intervention group divorced/widowed/separated LTFU than the control group and a higher proportion of married/co-habiting in the control group suggesting perhaps partner support may be a factor in completing the study, time constraints and motivation may also have been contributing factors. Although there is no evidence to demonstrate this, it could be of interest to follow up as understanding participants experience and views with regard to partner support may influence direction for future research.

6.4 *Weight loss at follow up*

This investigation has reported analysis on both intention to treat (ITT) and per protocol (PP) data for the primary outcome weight loss. The greatest weight loss was seen in the intervention group from analysis of the per protocol (PP) data, whilst the greater weight loss in the intention to treat (ITT) data was seen in the control group. Although not significant the ITT data showed a total weight loss of 2.1kg from baseline to follow for the intervention group and 2.9kg for the control group.

The per protocol data showed a between group difference total weight loss of 1.1kg which was significant 95% CI (-2.05 to -0.16), whilst the intention to treat data showed a total weight loss difference of 0.9kg which did not reach significance, 95% CI (-1.91 to 0.14). When adjusted for baseline weight both the ITT and PP data

showed there was a significant between group difference in weight loss, and the difference was greater in the PP data (section 5.2.2). Both the intervention and the control group (usual care) in the ITT unadjusted data showed a modest but not significant reduction in body weight, therefore, the intervention was no more effective than usual care on the primary outcome; change in body weight.

Although not a direct comparison with the HF2 study in terms of support/delivery of intervention, other lifestyle change intervention studies of 16 week duration which involved combinations of internet, face to face, group versus individuals, and the use of behaviour change techniques have shown weight loss of 2.9 to 5.5kg (180), however, unlike the control group in the HF2 study which achieved a similar level of weight loss, all of these studies involved more than a single contact. The implication of this is that delivering a single brief intervention in a screening setting offers an opportunity to achieve a similar weight loss to that shown in studies offering a multiple contact intervention.

Recent guidelines have established a 5% weight reduction after one year of treatment to be clinically meaningful in terms of evaluating the effectiveness of weight loss interventions (181,182) in populations at risk from obesity. The "Look AHEAD" study sample of overweight and obese individuals with type 2 diabetes incorporated a randomised controlled trial which delivered an intensive lifestyle intervention over four years, designed to achieve and maintain weight loss through increased physical activity and reduced calorie intake. The comparator group was given diabetes support and education consisting of three group sessions per year focusing on diet, exercise, and social support during years 1 through 4, the sessions were delivered annually thereafter (183). Following an observational period of up to

ten years and three months the results showed in both groups a strong relationship between glycemic measures and weight loss, with improvement beginning at 2.5% to 5% weight loss in patients with Type 2 diabetes. Systolic and diastolic blood pressure, HDL cholesterol, and triglycerides, improvement was shown to begin at ≥5% weight loss (183).

In terms of percent weight loss the ITT data in the HF2 intervention showed a 2.5% weight loss v's 3.3% in the usual care group, a mean (SD) difference of 0.8% (2.4)% (P=<0.005). Based on the results seen in the "Look AHEAD" trial, the HF2 weight loss results show there may be some a clinically significant benefits for both groups, however, other CVD risk benefits may not be seen until a ≥5% weight reduction (183). A systematic review investigating the maintenance of weight loss following lifestyle interventions combining diet and exercise showed that during these trials the intervention groups lost 9.5% of their baseline weight and 1 year after the intervention on average 54% of this weight loss was maintained (184), which is a similar percentage maintenance to previous reviews (185,186), which showed 50% maintenance at 1 year. While it remains unknown as to whether the weight loss in the HF2 study would have been sustained in a full 1 year period, it is promising to see the percentage weight reduction may, if increased over a longer period of time have the potential to show a significant future CVD risk reduction.

Studies selected for inclusion in a recent updated systematic review of interventions where the telephone was the principle method of intervention delivery concluded that, although there continued to be strong evidence for telephone-delivered physical activity and dietary behavior interventions for initiation of behavior change, the reporting of intervention implementation was less than optimal, with

approximately half of the studies not reporting on the length and number of calls completed, the training of staff, and inadequate reporting of methodology for the reader to interpret fidelity of the interventions (187). In contrast to these findings the HF2 study has reported on the number, the length, and described the individual components of the telephone calls in depth, adding to what is already known about lifestyle interventions using the telephone as the principle method of intervention (Appendix Q/Section 4.11.2). To date there have been no RCT's involving healthy volunteers, 40 years and over recruited to a lifestyle behaviour change intervention with the telephone as the principal method of delivery following CVD risk screening which could make a true comparison with the HF2 investigation.

6.5 HF2 Intervention versus brief intervention

The implication that the brief intervention (usual care) was sufficient to motivate both groups to reduce weight and the extra support given to the intervention group did not significantly increase weight loss supports the literature (section 3.5.1.8) for healthcare professionals to recognise opportunities for brief interventions as they arise and utilise behaviour techniques to encourage behaviour change (72). Perhaps the usual care group were more health conscious, and as they were not going to receive any further input from baseline to follow up they decided to take it upon themselves to be more proactive. As these are speculative reasons and not measured it is not possible to draw any conclusions as to the reason why the intervention was not successful in promoting a significant difference in weight loss in the intervention group compared to weight loss in the usual care group.

The percentage weight loss in both groups was clinically significant for the

unadjusted ITT data based on findings from the "Look Ahead" study, further supporting the need for all healthcare professionals to initiate brief interventions as the opportunities arise.

The delivery of the brief intervention (usual care) gave both groups the opportunity to discuss how to make realistic lifestyle changes to improve CVD risk with a health professional. Although the usual care group were not given additional monthly support they were aware they would return for follow up measurements in the same timeframe as the intervention group, which may have heightened their perception of social norms to include seeking behavioural approval either consciously or subconsciously which can in turn increase motivation (188). Evidence which supports that weight loss generally plateaus around 6 months (189), consequently, the duration of the HF2 intervention may not have been of sufficient time to reach a plateau and show a significant weight loss (188).

There were a sub group of participants from the TASCFORCE project who were invited to have an MRI scan post usual care to measure cardio vascular vessel atheroma. The number of participants in each group were equal (n=54 intervention and n=53 usual care), thus any comparable additional health messages were given to both groups. Less than 50% of volunteers in each group had the MRI scan, leaving the greater proportion of volunteers not having a scan suggesting it was not the necessarily the scan which was the motivator to engage with the intervention. It has not been determined whether having an MRI scan would have had any effect on weight loss in the investigation, this could be determined in future work.

In summary both groups showed a modest but not significant reduction in body weight, therefore, the HF2 intervention was no more effective than usual care on

the primary outcome; change in body weight. In terms of percent weight loss the results show there may be some clinically significant benefits for both groups, supporting the value of initiating brief interventions. For health professionals to initiate a brief intervention not only requires skills and resources to engage the individual to make changes but there is a need to provide ongoing and follow up support through the course of the behaviour change, which can become a lengthy process with implications for cost on manpower and resources in the short term, but producing the long term benefits of a healthier population.

6.6 Anthropometric Modifiable Risk Factors

6.6.1 BMI and Waist Measurement

BMI has traditionally been an indicator for measuring body size and composition; however, alternative measures that reflect abdominal adiposity, such as waist circumference and waist–hip ratio have been suggested as being superior to BMI in predicting CVD risk. The rational being that increased visceral adipose tissue is associated with a range of metabolic abnormalities such as decreased glucose tolerance, reduced insulin sensitivity and adverse lipid profiles, which are risk factors for type 2 diabetes and CVD (190).

At baseline a high proportion of male and females had waist measurements above the "increased relative risk level for metabolic syndrome" (190) (75.8% and 96.6% respectively). Mean BMI in the intervention group was 30.2 (kg/m^2) with 58.5% overweight and 41.5% obese and 30.4 (kg/m^2) in the control group, with 50.1% overweight and 49.2% obese. A significant between group difference was seen at

follow up for waist circumference (WC) -1.21cm (95% CI -6.021 – 0.90) but not for calculated BMI, with a greater reduction in WC seen in the intervention group (-4.0cm p=0.002) (section 5.3.1). Although still at "increased risk" a reduction was seen in the proportion of male and females WC (mean 95cm (57.6%) and mean 92.2cm (92.5%) respectively). Most behaviour change theories consider self-monitoring to be an important component of behavioural self-regulation (191). The intervention group were provided a tape measure and educational booklets to enable self-monitoring of waist measurement reinforcing the significance of reducing WC. Further as the intervention group showed the largest waist reduction and assuming that study compliance had been adhered to then it could be concluded that materials and prompts from counsellors did have an influence on reduction of WC further research would be required to test the hypothesis. The proportion of male and females with WC at "increased risk" had reduced from 75.8% to 57.6% and 96.6% to 92.5% respectively, which is encouraging, however, the reduction was not sufficient to bring them out of the "increased risk" category.

When predicting CVD risk the evidence is increasing to suggest that measures of central obesity that include a measurement of WC as well as BMI, should be considered for incorporation into the clinical assessment (192), as BMI does not distinguish between fat and free-fat mass therefore when used alone is not a sufficient indicator for CVD risk, and can misclassify some people as being normal weight or obese (193). Measuring WC alone does not overcome this issue but it can provide an independent prediction of risk in people who are normal or overweight, however, for individuals with BMI ≥35 (kg/m^2) evidence has shown measuring WC has little added predictive power of disease risk over BMI (194). A systematic review

examining measuring outcomes in weight loss studies concluded that body fat measurement is more metabolically informative than total weight and it proposed that measurement of visceral body fat should be considered a primary outcome of weight loss studies (195). The data presented from the review supported the conclusion that percentage body fat measurement or measure of fat mass before and after weight loss interventions which include both diet and physical activity components may be a more efficient and informative measure of change (195).

This investigation showed that reductions in waist circumference were statistically significant indicating that it may be a more sensitive to change than BMI which showed no statistically significant change despite weight loss having occurred. It may also be true that body composition had changed in the intervention group which could account for an increase in fat free mass showing no significant weight loss but a statistically significant reduction in waist measurement, particularly as increased levels of physical activity were seen at follow up (although not significantly). If this is the case then consideration for the intervention and its potential for physiological change is worth further investigation perhaps with some adjustments made to measurement of body fat.

Selecting the most appropriate method to measure central obesity is dependent on the nature of the research; measurement of BMI and the addition of WC as a measure of abdominal visceral fat was the most appropriate method to use in the HF2 study given the volume of participants screened, and is still considered a valid means of assessing weight change in a study with large numbers of participants (196).

The addition of body fat measurement methods such as skinfold measure, or bioelectrical impedance analysis (BIA) which are the least costly methods of assessment could have added another measurement to enhance the overall picture of CVD risk for the HF2 participants. It is a limitation of the investigation that body fat was not measured at baseline and follow up as the recent evidence in the literature strongly advocates its use (196). It could have been particularly advantageous to have utilized these methods of body fat assessment in the screening setting where the volume of participants screened in a single day and the repetition of the measurement task could lead to user error, particularly in the obese where it can be difficult to accurately measure waist circumference, however, the HF2 study personnel did adhere to standard operating procedures when carrying out these measures in order to eliminate such risk.

6.6.2 Blood Pressure

A significant reduction was shown in systolic and diastolic blood pressure (BP) in both groups from baseline to follow up -4.02 mmHg, (systolic BP) p=<0.001 in the intervention group versus -3.57 mmHg, (systolic BP) p=<0.001 in the control group, and a significant between group difference was seen in diastolic BP with the intervention group showing a greater reduction section (Table 17).

Increased weight is a strong indicator for hypertension (197). It seems, therefore, reasonable to assume the reduction in weight could be one factor responsible for the reduction in systolic and diastolic blood pressure in this investigation. Studies have also shown that realistic changes in diet and lifestyle can reduce average blood

pressure levels to a limited extent (2-3 mmHg diastolic) (198). As both intervention and control groups exceeded these levels of reduction from baseline to follow up, and the intervention group significantly reduced diastolic BP indicates the improvements seen in diet and physical activity could account for the reduction seen in diastolic BP.

Pulse pressure provides important predictive value for CVD events in middle aged adults who are normotensive or have untreated hypertension. It may have been a useful measure to have collected and to have included in the CVD risk discussion during the brief intervention. From ages 30 to 50 systolic and diastolic BP track together almost parallel, however, after the age of 60 systolic BP continues to rise whilst diastolic BP decreases, (199). This trend accounts for the underestimation of peripheral vascular resistance in older people and the large increase in pulse pressure seen in people over the age of 60 (199). Future analysis of pulse pressure and the increase in physical activity observed could allude to the possibility that the increase in physical activity seen in the intervention group was responsible for the significant reduction in diastolic blood pressure.

Published estimates have suggested that approximately one third of excess CVD and all-cause mortality can be attributed to elevated systolic blood pressure (SBP) at levels designated as non-hypertensive (200,201) indicating that benefits achieved from decreases in blood pressure are not limited to populations with hypertension (202). Meta-analysis from clinical trials looking for evidence of the benefits from even small reductions of blood pressure on CVD outcomes showed that a reduction of 4mmHg systolic blood pressure and 3mmHg diastolic were shown to reduce CV events by 15% and reduce relative risk of stoke by 23% in a cohort of 20,888 patients

comparing more intensive versus less intensive blood pressure lowering regimes (203). The HF2 intervention group showed a significant reduction in systolic blood pressure by 4.02 mmHg and diastolic blood pressure by 3.25 mmHg from baseline to follow up indicating a significant clinical outcome for the HF2 intervention. The elements of the HF2 intervention such as the behavior techniques used by the counsellors to increase motivation, set realistic goals to make small changes in diet and physical activity have affected a reduction in body weight and other parameters of diet and physical activity.

The improvements shown in BP can be attributed to dietary changes made in relation to the DASH eating plan (204) (**D**ietary **A**pproaches to **S**top **H**ypertension), a diet rich in grains, fruits, vegetables and low-fat dairy products, which the HF2 intervention counsellors encouraged participants to incorporate into a healthy eating plan. The HF2 intervention group saw a statistically significant increase in fibre intake (with the inclusion of wholegrains) (see section 5.5.2.2) and an increased intake of unsaturated fat (see section 5.5.2.1). Both groups significantly increased total number of fruit and vegetable portions in a 24hr period (see section 5.5.2.2) and saw a significant reduction in fat intake (see section 5.5.2.1). Increased levels of moderate physical activity in both groups, although not statistically significant, may also be considered a contributing factor for the improvements seen, as all of these factors are known to potentially modulate BP.

The HF2 intervention group participants were mailed a British Heart Foundation booklet containing healthy diet information. A section in the booklet discussed salt and gave details regarding recommended daily allowance as well as examples of

foods with high salt content; there also contained a section on food labelling and how to calculate salt levels on packaging.

Previous population targeted interventions showed a decrease in morbidity, mortality and healthcare costs with 1gram less of salt a day (205). It also showed that this type of intervention was feasible as evidenced from a UK salt reduction program where in 2006 the UK Food Standards Agency (FSA) introduced voluntary sodium reduction targets for more than 80 categories of processed food, which decreased mean sodium content in the food supply by 7% (206). Recent studies suggest that the UK's strategy has resulted in a significant but modest reduction in salt intake (207,208), although intake remained higher in lower SIMD groups, younger people, men, and ethnic minorities. It is evident, therefore, that future lifestyle interventions consider advice on salt reduction and that robust methods of assessing salt intake are adopted particularly in lower SIMD groups, young people and ethnic minorities. Dietary assessment of salt intake is time consuming and often underestimated, and although 24hour urinary assessment of sodium is likely to be more valid than dietary assessment, collection of 24hour urine involves considerable burden for subjects (209).

6.6.3 Lipids

Diet and lifestyle practices can affect concentrations of circulating serum lipids including; lack of physical activity, obesity, excessive alcohol intake, smoking and unhealthy diets high in saturated fats and salt, and limited or no fruit and vegetables, fibre, polyunsaturated and monounsaturated fats (210). The next

section will discuss some of the changes seen in serum lipid concentration in the HF2 study sample.

There was a significant between group difference seen in levels of total serum cholesterol and low density lipoprotein (-0.27 mmol/L, 95% CI -0.45 - 0.09, p=<0.01) and (-0.22 mmol/L, 95% CI-0.41 to -0.01, p=<0.05) respectively with the intervention group achieving a higher reduction, this is consistent with reported improved dietary outcomes in the intervention group including a decrease in total fat and increase in unsaturated fat intake. Although both groups reduced total cholesterol and low density lipoprotein serum levels significantly, the significant difference between groups indicates some success for the intervention; it also shows perhaps that both groups had become more health conscious.

Statistically significant increases were seen in high density lipoprotein from baseline to follow up in both groups but there was no between group difference. The intervention group increased number of days per week physical activity was taken and both groups increased the number of participants achieving the recommended 150 mins/ week moderate activity, 30.2% to 31.6% (p=0.493) in the intervention group and from 17.4% to 22.7% (p=0.866) in the control group which achieved the greater increase. However, the increase was not significant between groups concluding that despite increased levels of HDL in both groups the intervention was not successful in bringing about a sufficient change or indeed a significant increase in levels of physical activity between the two groups. Both groups had reduced their intake of total fat so it is unlikely that dietary fat intake would have contributed to the increase in HDL. Change in alcohol levels may have been a confounder, where the intervention group saw the number of drinks per day stay the same, the number

of days per week consuming alcohol had reduced, conversely the control group saw the number of days per week consuming alcohol remain the same whilst the number of drinks per day reduced which may also have contributed to the increase in HDL levels in both groups.

A review examining the effects of aerobic exercise, resistance training and combined aerobic and resistance training on cholesterol levels and lipid profile, concluded that a dose–response relationship between levels of HDL cholesterol and physical activity exists (211), and that regular physical activity consisting of a weekly caloric expenditure of 1,000 kcal or more per week is reported to increase HDL cholesterol. Recommendations from the review advocated to improve and maintain lipid levels, a combination of low-intensity resistance training, prolonged moderate-intensity aerobic exercise combined with an increase in physical activity to 5 days of 30 mins was required (211). The HF2 counsellor telephone calls provided motivational support through setting achievable weekly targets, providing a pedometer to measure success and encouraging social support, reinforcing the association and importance of regular physical activity and increasing levels of HDL (212). At follow up the intervention group had increased the number of days per week of vigorous activity by 6% from baseline and by 23.1% for number of days per week of moderate activity. Both groups increased the numbers of participants reporting having achieved the recommended levels for moderate activity with the control group achieving the greater increase (section 5.6.3).The HF2 study has shown a dose response effect with increasing levels of physical activity and increased levels of HDL, which could account for the modest changes, however, the intervention did

not bring about sufficient change in physical activity levels to see a significant between group effect.

Factors which may have influenced these findings could be related to the limitations of self-reporting, over and under estimating levels of physical activity (213). The IPAQ questionnaire quantifies activity as carrying light /heavy loads, cycling and playing tennis into vigorous and moderate exercise which could be considered to be either vigorous or moderate, depending on the individual. Unless an exercise regime where levels are easily quantifiable for example 60 minutes of high impact aerobics can clearly be viewed as vigorous activity, or the use of objective measures such as accelerometers, quantifying the number of minutes per week may prove difficult for an individual to report (214).

6.6.4 Blood Glucose

Mean non fasting blood glucose levels had statistically significantly lowered in the intervention group from baseline to follow-up from 5.35 mmol/L to 5.17 mmol/L a reduction of -0.17 mmol/L (p=0.04). As discussed in section 6.4 with reference to the "Look Ahead Study" a strong relationship was seen between glycemic measures and weight loss (183) indicating that the 2.5% weight loss seen in the HF2 intervention group could be directly attributed to the 3.2% reduction in blood glucose, which is a notable finding and clinically significant (183), however, there was no significant between group difference. Random blood glucose measures were used as participants were attending for screening throughout the course of the day, therefore, making it unreasonable to fast. Random blood glucose testing is a valid

method to include in the assessment of cardio vascular risk in this investigation as it is relatively inexpensive, suitable for large numbers in screening studies and requires no further blood sampling as a sample had already been acquired for the lipid profile. Blood glucose levels tend to remain within a normal range below 6.9 mmol/l, however, post prandial blood glucose level can rise up to 7.8 mmol/l or more, temporarily, in non-diabetics highlighting the limitations of acquiring non fasting samples.

The test for levels of glycated haemoglobin (HbA1c), which identifies average plasma glucose concentration, is also convenient as no fasting is required. It measures average blood glucose control over a period of 2 to 3 months. HbA1c provides a longer-term trend, similar to an average of how high blood sugar levels have been over a period of time and can be used to reflect average blood glucose levels over that duration, providing a useful longer-term gauge of blood glucose control (215).

The HbA1c test was not used in the HF2 study as it is relatively more expensive than random blood glucose testing and although used in health surveys it is more commonly used for monitoring glycemic control in diabetic patients. As blood glucose testing was not the primary outcome for the study it was considered justified to use the validated relatively inexpensive test which met the aims of the investigation.

6.6.5 CVD Risk

The impact of providing CVD risk assessment on a person can prove complex and is likely to be affected by factors such as beliefs about the disease, prior knowledge, and peer comparison (216). A recent systematic review has shown that providing

patients with CVD risk information and education has shown to change risk perception and increases the accuracy of perceived risk (217).The HF2 investigation showed both groups 10 year calculated Framingham CVD risk scores to be relatively low at baseline; 4.1% for the intervention group and 4.9% in the control group at baseline (Table 5.17) than for the average risk estimates derived from the Framingham Heart study (159). However, the HF2 sample did not include participants with a risk score >20%.

Both intervention and control groups had statistically significantly reduced their 10 year CVD risk score at follow up to 3.3% (p=<0.001) and 4.0% (p=<0.001) respectively which could be considered clinically significant. There was no statistically significant between group differences to suggest the intervention was effective in adding to that risk reduction. As the risk score is calculated it would seem logical that the improvements observed in both groups for total cholesterol, HDL, and systolic blood pressure (those being the only changeable values entered into the calculation) that a lowering of mean CVD risk score would be seen. Communicating CVD risk involves helping participants to understand the meaning of that risk and offering support in particularly to those at high risk, and to make lifestyle changes to reduce that risk. If the information is not provided in a way the patient can understand, then the desire and ability to initiate change is likely to be limited (217).

There are three validated means of predicting 10-year risk for cardiovascular disease in the UK; Framingham (159), ASSIGN (218), and the QRISK, (219) the latter of which is reported to be less likely to overestimate risk in the UK population (220). The choice to use the Framingham score in this investigation was historical as the HF2 study was nested in the TASCFORCE study which was ongoing so it was not an option

to consider using a different method. A random 10% sample of participants from each group were chosen to recalculate 10 year risk using the QRISK score in order to compare with the Framingham scores to determine if they were significantly different. The updated QRISK 2-2016 (221) risk calculator was used for the calculations. The findings showed there was no statistically significant difference between the two scoring methods in both the intervention and control group, which justified the use of Framingham in the investigation. However, when calculating the Framingham score SIMD was not included in the original Framingham equation and was, therefore, not included and in the sub analysis with the QRISK calculation. To add SIMD in one calculation and not the other would not have given a comparable result. It is a limitation of this investigation that SIMD was not included in the Framingham CVD risk calculations as the effects on cardiovascular risk of social deprivation are well documented and in excluding this measure the Framingham algorithm may have underestimated CVD risk for participants in the most deprived groups (222).

Modest reductions in a number of physiological parameters resulted in modest reductions in overall CVD risk. The significant reduction in CVD risk score seen in both groups can be attributed to the combination of lowering WC, BP, TC, non-fasting blood glucose, and the increase in HDL, however, the between group change was not shown to be significant and this may be as a result of the sample size which was powered to detect the primary outcome, weight loss, only. A longer study duration may also be required to see statistically significant and clinically meaningful between group physiological changes.

Abnormal lipid profiles are risk factors for CVD's and thus assessment enables early

diagnoses of abnormal levels enabling earlier intervention to reduce risk (223). This study showed both groups significantly reduce their total cholesterol levels; however, the reduction in the intervention group was significantly greater than in the control group (-0.27 mmol/L p=0.003). The difference may be attributed to, however small, the benefits of the statistically significant increase in dietary fibre, specifically soluble fibre, intake in the intervention group, and although not statistically significant between groups; the increase in physical activity levels, both of which have total cholesterol and Low density lipid lowering benefits (224, 225).

There were no improvements seen in triglyceride levels, where both groups' levels were similar at baseline and follow up (table17). The participants in this study were both fasted and non-fasted. Without data to distinguish fasted from non-fasted it would not be possible to say if this would have made a difference to the results. The improvements seen in diet and physical activity along with modest weight reduction may not have been enough to reduce triglyceride levels but may have been sufficient to prevent any increase. The sample was also perhaps too small to detect a change, as the study was not powered to detect a difference in levels of triglyceride.

There can be significant variation in level of triglyceride measures depending on whether the person has fasted as levels can be substantially increased in the postprandial state (226). There is some evidence to suggest that postprandially levels are a more robust indicator of CVD risk, as the greater variability of levels in the postprandial state captures important information about an individual's metabolism (227). A recent study reported on findings refuting the need for fasting and non-fasting triglyceride measurement and questioned the usefulness of fasting samples in a screening setting where establishing an initial level would be the

primary objective, fasting may then be of more importance when going on to establish a diagnosis of genetic dyslipidemias (228).

NICE guidelines recommend having CVD risk, including cholesterol levels checked every 5 years in adults between the ages of 40 and 74 (229). NHS Health Checks were introduced in England in 2009; the purpose of the screening program was to tackle avoidable deaths and disability, reducing health inequalities and identifying undiagnosed health risks (230). However, the impact of the program is dependent on uptake and there is evidence that socio-economic deprivation is associated with lower levels of screening participation (231, 232). It is essential that lower socio-economic groups are targeted as inequitable attendance at screening has the potential to widen existing inequality (232).

In Scotland the Keep Well program, also screened for undiagnosed health risks, namely hypertension, abnormal lipids and elevated blood glucose levels targeting 40-64 year old individuals, initially in the most socio-economically deprived areas (233). In all areas the percentage of individuals attending screening reduced with increasing deprivation, although the absolute numbers of targeted individuals was greater in the most deprived quintile (233). Both the NHS checks in England and the Scottish Keep Well programs indicate a continued need for CVD risk screening in lower socio-economic groups, so that risk is not left undetected. The HF2 study was successful in attracting almost 25% (24.3%) volunteer participants from the highest deprivation category (12.3% less than the medium and 14.7% less than the low deprivation categories), possibly as a result of the diversity in recruitment sites which were targeted. Therefore, as there were modest but significant changes seen in some of the HF2 study's outcomes such as reduction in weight, waist

circumference, lowered blood pressure, improved lipids and overall CVD risk scores, this type of intervention appears to be worthwhile, as it was shown to attract a substantial number of volunteers from socio-economically deprived areas, however, a period of follow up would be required to evaluate change over time.

6.5.6 Cardio Vascular Risk Perception

There were no significant changes between groups perceived risk of developing CVD in the coming 10 years from pre to post screening. However, differences were seen in gender, with males more likely to report a higher perceived risk of developing CVD ($p=<0.01$) at baseline. There was no significant difference between the intervention and usual care groups in both thinking risk was average to lower than average, however, females significantly considered their risk to be lower than the males following screening $p=<0.05$ (Table5.16)

Women have been shown to believe incorrectly that they are more likely to die of breast cancer and do not perceive CVD as the greatest threat to their health (234) despite cardio vascular diseases accounting for 33.2% of global causes of death in women, two thirds more than cancers (235). Coronary Heart Disease has a higher prevalence in males within each age stratum until after 75 years, which may contribute to the misconception that heart disease is a man's disease (236). Complex explanations about cholesterol and CVD risk alone may not be sufficient for motivating behaviour change. CVD risk communication has to be meaningful and salient to the individual's circumstance. Self- Regulatory Theory explains that people's perception of health risk is based on perceptions of a particular illness or disability, which creates the development of their own representation of illness risk

(129). In the HF2 brief intervention (usual care) the risk perception is realized in discussion around the 10yr risk score of developing CVD together with the physiological measurements, making it meaningful to the individuals own risk. Through utilizing behaviour techniques the investigator can then assist participants to identify their risk factors and decide the changes necessary to improve their risk. The initial brief intervention discussion also facilitated both groups to consider the individual changes required to be made through the course of the 16 week investigation.

Although both intervention and control groups significantly reduced their CVD risk scores, these results were not defined by gender, something which could be looked at in future analysis. However, given that the HF2 investigation showed CVD risk perceptions reflecting women's risk to be lower than men's indicates a need to emphasis the risks of CVD in women of middle age in future interventions, particularly if women continue to hold the view that CVD is a lesser threat to their health than to men.

6.7 Influences on Weight loss

6.7.1 Marital Status

It is important to consider which social characteristics may have influenced weight loss in order to identify predictors for targeting future interventions. Marital status was shown to be a predictor for weight loss in the HF2 investigation. In both groups the greatest weight loss was seen in the widowed, separated or divorced category, with the greatest weight loss in the intervention group, indicating that perhaps it may be easier to modify lifestyle change when not considering a partner, particularly

if the partner does not wish to make changes. However, a recent review assessing the effectiveness of pragmatic lifestyle interventions in routine practice for the prevention of type 2diabetes showed that encouraging engagement of social support maximized a reduction in blood glucose in intervention arms compared to the control arm (237). As there were a greater proportion of participants not married or co-habiting perhaps the social support given by friends and family may have been a contributing factor in the greater weight loss seen in the intervention group.

The married or co- habiting group made up the largest proportion of the sample at 77% whilst the widowed, separated or divorced comprised of 15%. It is difficult to draw any conclusions from these results without considering the effect of marital transitions which have been recently thought to be more important than marital status in predicting body weight change (238). The loss of a partner, the stress of dissolution of a marriage and living alone have all been associated with an increase or decrease in body weight, therefore, further investigation as to individual reasons for weight loss would be needed in order to reach a firm conclusion.

6.7.2 Employment

The largest proportions of participants in the HF2 sample were either employed full time (54%) or retired (22%). The smallest weight loss was seen in the largest category the employed full time whilst the largest weight loss was in the retired, indicating, perhaps the retired had more time to focus on lifestyle improvement (239). There is evidence to suggest that many retired people leave the UK to live in the sun for a period of time during the winter months where there is the opportunity to be more active outdoors (239), however, that would not explain why

the intervention group achieved the greater weight loss. The intervention group had 30 minutes telephone contact time with their counsellor per month which may have contributed to increased motivation over the 16 week program and maintained focus on reducing weight. The intervention group also lost more weight in the months December through to February which may have seen the effect of retired people using the daylight hours to get out and be active while the full time people may not be as motivated due to travelling and leaving work when it is dark (240).

Retirement increases leisure time, which may reduce physical and mental stress, improving both subjective well-being and health (241) and investment in health may increase as retired individuals have a lower marginal value of time (241). In addition, it is known that people are more receptive to health messages during life transitions (242). These results have shown that the retired group has been receptive to the HF2 intervention perhaps as a result of having more time to focus on the intervention, and a desire to invest in improving health. The implications for future research would suggest that the pre-retiral or retired would be a worthwhile group to target for this type of intervention, or that there needs to be more consideration to approaches used with people who are in full time employment.

6.7.3 Seasonal Effects

The greatest weight loss by seasonal grouping was seen in December through to February in the intervention group (2.9kg) and March through to May in the control group (1.6kg) with the intervention group seeing the greatest weight loss over all the seasonal groupings. It could be argued that the weight loss seen in the intervention group during the seasonal grouping December through to February is surprising given that it includes the Christmas holiday period, but perhaps counsellor support

over this period increased motivation to be more aware of weight gain over this period and introduce behaviour techniques to avoid weight increase. The seasonal group also included January and February which are often associated with making resolutions to reduce weight and improve diet and increase exercise for many people (243). A prospective study involving healthy subjects completing one year of observation, looked at whether weight gain occurs as a result of small, steady increases in weight throughout the year, or because of more discrete periods of increased energy intake or decreased energy expenditure that might occur, such as holiday periods or during particular seasons (244). It showed that weight increased by 0.32kg during a six week winter holiday period, and 0.62 kg over the entire year, suggesting that the period contributing most to yearly weight change was during the six week holiday (244). It also showed that despite the fact that more than 85 percent of the study subjects made no efforts to control their weight, large weight gains over the winter holiday season were not the norm (244), supporting Jebb's work suggesting the body's "in built" mechanism for regulating weight control (245). The study also found that those who had a major holiday weight gain, were more likely to be overweight or obese and such weight gain may be clinically important, particularly for those who are already at-risk for obesity-related comorbid conditions (244) which again substantiates Jebb's theory of the need to adopt cognitive restraint in the present day where the environment, high energy density rich diets, and sedentary lifestyle have destabilized the body's natural ability to self-regulate weight (245).

The control group also lost weight in the period December through February (1.4kg), although marginally less than their greatest loss of 1.6 kg in March through May. The

spring months are often a time where people become active in the garden, and there is an increase in daylight hours, which can bring an opportunity to engage in physical activity (240). The extra support from the counsellors may well have made the difference between the two groups, therefore, the HF2 study results show that with support it is possible to reduce weight over a period which is often considered difficult to reduce weight (243)

6.8 Changes in Diet and Lifestyle Behaviours

6.8.1 Views on Initiating change

In considering the outcomes regarding weight loss, the success of the intervention and the importance of theory of behavior change, it is important to look at participant's views on initiating change together with the Transtheoretical Model of Behaviour Change (TTM). There was no significant difference between groups at base line or follow up regarding views on initiating change in diet. In both Intervention Group and Control Group the majority of participants had "planned to start eating a healthy diet". A higher proportion in the intervention group (9.8%) were hoping to start in the next month, and (7.5%) more in the intervention group felt "somewhat" or "mildly confident" in sticking to the plan at baseline. The findings indicate that while both groups were at the stage of contemplation within the stages of TTM a higher proportion of people in the intervention group were somewhere between contemplation and preparation in making the decision to start at a defined point.

At follow up fewer people said they planned to eat a healthy diet, with marginally more (1.8%) in the control group than the intervention group, which was perhaps because both groups had already started eating a healthy diet or perhaps the IG

group had not progressed between contemplation and preparation. The control group felt "very confident" (21.5%) in comparison with the intervention group (18.7%) and there were more in the control group who went on to continue eating a healthy diet 76% v's 74.6% (Table 5.9) indicating a continuing progression through the stages of change in this group.

Improvements in diet were seen in both groups, which may have contributed to the higher confidence levels seen at follow up. There was no difference between the groups in their views about readiness, timescale and confidence in initiating dietary change, however, there were more people in the control group who continued to feel "very confident" and "continuing to eat a healthy diet" than the intervention group.

The intervention did not produce a significant change in motivation and perceived confidence to initiate and maintain a healthy diet, however, the changes which did occur were sufficient to contribute to a weight reduction and show improvements in all measured CVD risk factors, with the exception of the intervention group's triglyceride levels which marginally increased, indicating that perhaps the intervention group had underestimated their confidence to bring about change.

It may be the case there were not enough sessions or frequency of calls to maintain motivation particularly in people reporting not feeling entirely confident at the start of the intervention. More flexibility may have been required in the delivery of the different elements of the program. In the intervention group, the sessions were delivered by experienced nurse counselors trained in behaviour change theory and delivery of behavior change interventions. The sessions incorporated a number of behaviour change techniques such as motivational interviewing, goal setting

(including individual diet prescriptions), and relapse prevention, other studies have incorporated the expertise of clinical psychologists (246).

Motivation and confidence are key determinants of behaviour change (247). The counsellors implementing the HF2 intervention were trained to assess an individual's readiness for change and explore participants beliefs about the benefits from improved health and the consequences of not making changes to improve and preserve future health (as reviewed in sections 3.6.3 and 3.6.4, Trans theoretical Model and TRA Model). Behavioural techniques are then applied such as motivational interviewing, goal setting, feedback and relapse prevention strategies appropriate for the individuals need. (Appendix Q).

Both groups began with similar levels of confidence and motivation, however, the control group continued to feel more confident and continued to eat a more healthy diet at follow up. The difference between groups was not significant, and there was no follow up period to estimate if the level of confidence and motivation would continue, however, there may be scope for further research to explore which aspects of the brief intervention impacted on the control group to enable them to feel more confident and continue to eat a healthy diet at follow up.

6.8.2 Dietary Changes

Analysis of various dietary components and the changes in intake of these over the course of the intervention can help with interpretation of the changes seen in

weight and other CVD risk factors. These changes are discussed in the following sections.

6.8.2.1 Fat Intake

The dietary advice for management of body weight given by the HF2 counsellors consisted of total calorie intake control, with recommendations to increase consumption of lean meat, fish, whole grain cereals, low-fat dairy, and fruit and vegetables, whole grain cereals and fish (248) .

With regard to dietary fats, it has been suggested that the replacement of 1% of energy from saturated fat with polyunsaturated fatty acids will lower low density lipoprotein cholesterol, which could reduce incidence of CVD to 2 to 3% (249). The counsellors delivering the HF2 intervention encouraged participants to make changes in the type of fats consumed (i.e. saturated fat replaced by unsaturated fat), or changing the type in combination with an overall reduction of fat in order to increase protection against cardiovascular events.

At baseline both groups' total fat scores were in the low category with a score less than 30 which represents a fat intake of 83g per day or less corresponding to 35% of the energy RDA for an average woman (250). The results from the dietary questionnaires correlated with the views expressed on initiating change in diet at baseline. Both groups significantly reduced their total fat intake, the intervention group by 20% and the control group 14.9%, however, the degree of change was not significant between groups. Unsaturated fat intake scores increased in the

intervention group and decreased in the control group, however, neither groups change was significant nor was there significant difference between groups see section (5.5.2.1). The results show that the moderate weight reduction seen in the intervention group could be attributed to reduced energy intake and the increase in unsaturated fat intake and significant decrease in total fat intake contributing to an overall improvement in dietary fat intake.

A recent report into people's attitudes towards diet and health in Scotland indicated that there was an awareness of the main healthy eating messages and in particular those messages relating to eating plenty of fruit and vegetables, limiting foods and drinks that are high in sugar and salt, and reducing between meals snacking. However, there was lack of clarity with specific consideration of the fat, salt and sugar content of foods cited by only 4% of the sample as a primary influence on food choice, and only a third of respondents mentioning it as a factor at all, suggesting that whilst there is claimed awareness of healthy diet messaging, the majority of adults had not accepted the significance of the specific nutrient based messages or incorporated them into their behaviour when making choices regarding dietary intake (251).

Reference to current British Heart Foundation booklets were used as an aid to guide discussion regarding fat content in participant's diet during delivery of the brief intervention (usual care). The intervention groups' increase in unsaturated fat intake may have been as a result of continued scrutiny of participants diet by the counsellors and continued reinforcing messages over the duration of the intervention maintaining motivation to make changes by increasing awareness of specific dietary fat content and interpretation of nutritional food labels.

To summarise the improvements in specific types of dietary fat intake appeared to affect the intervention group's blood lipids decreasing total cholesterol, low density lipids and triglyceride levels as well as increasing high density lipids. Increasing unsaturated fat intake also lowered the intervention group blood glucose levels preventing insulin resistance, and reduced systolic and diastolic blood pressure and overall CVD risk score (224).

6.8.2.2 Fibre Intake

The Scientific Advisory Committee on Nutrition reported on the evidence for the association of dietary fibre and CVD (252). The report indicated a biologically relevant association between higher consumption of insoluble fibre such as high fibre breakfast cereals, wholemeal breads, pasta, nuts and seeds, vegetable fibre and whole grains but limited evidence of the effect of increased soluble fibre such as oats, pulses and root vegetables and fruit fibre and CVD events (252).

At baseline both groups fibre intake score was low, less than 30 which corresponds to a fibre intake of 20g/day or less. Whilst the intervention group increased their fibre score significantly out of the low category the control group reduced their intake. The change in intake between the groups was significantly different, see section 5.5.2.2.

There are many important physiological effects associated with the intake of dietary fibre including controlling blood sugar levels by slowing digestion and the absorption of carbohydrates, thereby, lowering the rise in postprandial blood glucose and the insulin response. Isolated viscous fibres such as pectin, rice bran or oat bran lower both total serum cholesterol and low density lipoprotein levels (252). The

intervention group showed a significant decrease in both total cholesterol and low density lipoprotein levels and a decrease in both systolic and diastolic blood pressure consistent with an increase in dietary fibre. There was also a significant between group difference showing the intervention was successful in bringing about a physiological change, which is encouraging. Reasons for this increase may have been scrutiny of dietary behaviours by counsellors and providing educational materials that reinforce messages about healthy eating, reinforcement of the importance of dietary fibre and the health benefits which come from it, including improved cholesterol levels (253).

6.8.2.3 Fruit and Vegetable Intake

The World Health Organisation advice for adults is to consume at least five varied 80g portions of fruit and vegetables per day (10). The Scottish Health Survey (SHS) reported the average adult intake of fruit and vegetables in the 2014 survey as 3.1 portions per day with I in 5 adults (20%) and 1 in 10 adults (10%) of adults not taking any fruit and vegetables (254). Both intervention and control groups significantly increased the total number of fruit and vegetable portions taken over a 24hr period. The results from the HF2 study has shown both groups having a high intake of fruit and vegetables, above the recommended levels at baseline and follow up with a significant increase from baseline in both groups, however, the difference between groups at follow up was not significant. One of the reasons for the above average reporting of number of portions may be the difference in reporting methods from the SHS and participant's perception of portion size (255) which was constant at both time points for both groups.

Whilst fruit and vegetable intake was high at baseline the increased intake at follow up which in turn increased dietary fibre intake could be linked to improvements seen in the intervention groups CVD risk factors. The control group fruit and vegetable intake was also increased but marginally less than the intervention group intake, however, the reduction seen in fibre intake showed that although the fruit and vegetable intake was high, and the change from baseline to follow up was significant the reduction in fibre intake was not enough to show improvements in CVD risk factors to the same extent as the intervention group.

The SHS question to assess fruit and vegetable intake was asked in such a way as to aid visualisation of what a portion size is, for instance, tablespoons of vegetables, cereal bowls full of salad, handfuls of small fruits (e.g. raspberries) but it was still felt there may have been some variation between participants' interpretation of a portion (255). Inaccurate reporting can lead to inaccurate interpretation and dissemination of results, as noted in a study where using a food diary showed a significant correlation between saturated fat intake and breast cancer, but using a food frequency questionnaire found there was no significant correlation (256). Ideally recall and completion of dietary questionnaires would be carried out face to face with standardized measuring equipment or photos to eliminate recall bias which has cost implications. The resulting high estimation of fruit and vegetable intake in this study is possibly due to self-reported over estimation or difficulty in distinguishing portion size particularly as both intervention and control groups scoring was high and both groups had received the brief intervention prior to "baseline", however, the results show consistent improvements in all CVD risk

factors, indicating that the dietary improvements have affected the physiological outcomes and as well as a reduction in body weight.

6.8.2.4 Sugar Intake

Higher intakes of sugar, in particular sugar-sweetened beverages (SSB) are associated with weight gain and increased levels of triglyceride. There was no association between group allocation and change in number of sugary drinks consumed, or change in number of teaspoons of sugar consumed per day, however, the intervention group did show a significant reduction from baseline to follow up from 1.0 to 0.5 of a spoonful p=0.029 (Table 5.11), which is encouraging as sugar consumption was discussed in the context of eating a healthy balanced diet. The majority of particpants in both groups had not changed the number of drinks consumed from baseline to follow up (57.7% IV versus 55.6% CG), there were similar proportions in both groups who had decreased the number of drinks and slightly more increased drinks in the control group (Table 24). The results are comparable with the 2014 SHS findings for this age group showing a slight increase or no change in overall sugar consumption (254). The UK March 2016 budget saw the planned introduction of a sugar tax on soft drinks, to come into force April 2018, adding around eight pence to a can of sugar sweetened beverages (SSBs) in an attempt to save a generation from the toll of obesity. One study estimated that a 10% tax on SSBs was predicted to reduce the percentage of the overweight or obese adult population by 0.7%, equating to 14,380 adults (257).

6.8.2.5 Alcohol Intake

Intake of alcoholic beverages is not only an independent risk factor for CVD by reason of the influence of alcohol on blood pressure and increased triglyceride levels, it also contributes to a high energy intake and weight gain (258). At follow up the intervention group reduced drinking in the 2 to 4 times per month and 2-3 times per week category but the control group levels remained the same (Table 5.12). The intervention group saw the number of drinks per day consumed stay the same whilst the number of days per week consuming alcohol had reduced, conversely the control group saw the number of days per week consuming alcohol remain the same whilst the number of drinks per day reduced. Possible reasons for the difference seen in the groups may be that the intervention group were adhering to advice given by the counsellors to have at least 3 days free of alcohol (259), whilst the control group also wanted to reduce alcohol but they decided to reduce the number of units per day indicating an overall alcohol reduction in both groups which was not significant but none the less encouraging and likely to have contributed to the reduction in body weight in both groups.

The intervention group were given an interactive device for measuring the alcoholic unit and calorific content in commonly consumed alcohol brands, as the intervention group reduced more weight than the usual care group the device combined with regular added motivational support, reinforcing health messages on benefits to health from counsellors, may have influenced participants awareness of units and calorific intake not only to reduce alcohol intake but to reduce body weight, however, with no significant change in alcohol consumption between groups the intervention may not have been responsible for the changes seen. Reasons for

this may be that changing alcohol drinking behaviour requires intensive strategies to be implemented (260) and this was not in the scope of this intervention. The Institute of Alcohol Studies report in 2012 showed a continuation of the trend in consumption frequency that sees older people drinking most often of all age groups. Since 2006, 45–64 year-olds have been shown as most likely to consume alcohol in the last week, and 65+ year-olds have been most likely to do so on 5 or more days over the same time period (261). Older drinkers (45–64 and 65+ year-olds) were most likely to consume alcohol most frequently. Self-reported estimates of alcohol consumption are generally considered to be subject to various biases and typically produce consumption estimates much lower than those based on objective alcohol sales data (262)The HF2 intervention was not powered to detect change in alcohol intake; however, the reduction in number of days per week drinking is encouraging. Future investigations could examine participant's perception and awareness of alcohol consumption and calorific intake and its relationship with CVD disease and weight gain to inform future interventions tailored to focus on these factors.

6.8.2.6 Smoking Habits

Although the numbers of smokers in both groups were small, smoking is still the leading behavioural risk factor for CVD (263). The effects of smoking increase blood pressure (264) and the way in which the body processes cholesterol enabling greater amounts to remain in the blood circulation decreasing the ratio of high density lipids to low density lipids (265,266). There were no differences in smoking status between groups at baseline, p=0.858. Of the nine smokers in each group one participant per group had stopped smoking at follow up. The actions taken by the Scottish Government to tackle the harm caused by tobacco included legislation to

prohibit smoking in public places, which came into effect in March 2006, raising the age of sale for tobacco from 16 to 18 in 2007, implementation of a tobacco retail register in 2011, a ban on self-service sales from vending machines in 2013, and the introduction of a tobacco display ban in shops from 2013.

The decline between 2013 and 2014, from 23% to 20%, is the sharpest year-on-year reduction over the full time series. This follows a period between 2011 and 2013 when smoking rates were relatively stable at 23% (254). The combination of these strategies appeared to have an impact on levels of smoking in Scotland but there are/were disparities in social status and smoking with still one in three (34%) adults in the 20% most deprived areas in Scotland smoking cigarettes, significantly higher than 9% of those in the 20% least deprived areas (254). Discussions around CVD risk factors and the effects of smoking were introduced in the HF2 intervention and recommendations were given for smoking cessation in line with current NICE guidelines (267). As the study sample had a small proportion of smokers, it would not be possible to derive a meaningful effect from the intervention.

6.9 Changes in Physical Activity Levels

6.9.1 Views on Initiating change

Undertaking regular physical activity is an important component of total daily energy expenditure (268). It can affect energy balance by creating an energy deficit through increased energy expenditure which in due course can produce weight loss and enable weight maintenance (269). Regular physical activity can also help control certain CVD risk factors lowering blood pressure and triglycerides, raising HDL and

managing blood sugar and insulin levels and lowering the risk of type 2 diabetes (270). Questionnaires were completed to assess participant's views with regard to readiness and confidence in increasing physical activity levels. Both groups began with similar levels of confidence and motivation (section 5.6.7), however, the intervention group continued to feel more confident and reported to continue to increase levels of physical activity at follow up, implying that the HF2 intervention encouraged motivation and confidence, showing a degree of success with the behaviour techniques deployed, such as the agreed physical activity targets, using the pedometer to incentivise and continual feedback and re-evaluating progress, however, with no follow up period it is not possible to estimate if the level of confidence and motivation would continue. Consistent with the greater improvements in confidence in improving diet reported in section 5.5.1, the intervention group also reported a greater increase in their physical activity levels, which may have been as the result of increased confidence and acquired self-efficacy as a result of the counsellors' support.

Both groups were similar in reporting the number of days per week of vigorous physical activity at baseline. At follow up the number of participants in the intervention group reporting no vigorous activity dropped by 6% and increased by 1.6 % in the control group. The intervention group were set physical activity goals with the use of a personalised physical activity prescription including set goals for number of minutes per week of levels (vigorous, moderate and walking) of activity. This may have been enough to motivate more people in the intervention group to start vigorous activity compared to the control group who had increased the

percentage reporting no vigorous activity indicating a degree of success for the intervention.

To summarise there was no significant difference between groups in number of days per week and more importantly, number of minutes per week in the amount of vigorous activity taken, indicating that the HF2 intervention itself was unsuccessful in bringing about an increase in levels of vigorous physical activity, however, it was successful in increasing a percentage of participants who had not previously undertaken vigorous activity to start.

Overall between baseline and follow-up it is encouraging to note that the percentage of participants achieving the recommended 150 minutes of moderate intensity activity per week increased for both groups, with the control group achieving the greater increase, although this was not a significant between group difference (Figure 5.6).

6.9.2 Walking

Walking was defined as "at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure". The intervention promoted walking as the main activity as a pedometer and a walking plan were provided. There was no significant difference between groups in change in walking behaviour, however, walking was included as a separate variable as it forms part of 'moderate intensity' activity.

A percentage of participants (6.1%), recalled having no walking activity at baseline in the past 7 days indicating a misperception of what precisely was meant by walking activity. The question did refer in part to walking at home but it is possible that a

proportion of participants when thinking about physical activity immediately consider organised or vigorous exercise and not at work and at home, walking to travel from place to place, which they may be carrying out but not achieving a moderate level of intensity. The limitations of self-reported walking activity and unedited data entry is apparent, as it is unlikely that participants have not walked at all in a 7 day period given all were physically mobile. The possibility of reviewing the form to clarify certain points could be way of possibly counteracting this shortcoming, however, it would be time consuming. The addition of an accelerometer which can be set to measure the number of accelerations per minute would have enabled a more accurate estimation of levels of walking activity. The advantage over a pedometers being that although more expensive in terms of cost and researcher burden they are less likely to influence physical activities as people become accustomed to checking their pedometers and working to increase or manipulate their physical activity according (271).

6.9.3 Sedentary behaviour

A relationship has been shown to exist between prolonged periods of activity involving sitting or reclining, and all-cause mortality and cardiovascular events independent of moderate-to-vigorous physical activity (272). Analysis has shown that more time spent in sedentary behaviours has been linked to increased risk of mortality, CVD (273), impaired lipid and glucose metabolism (274,275) and metabolic syndrome (276).

There was no significant difference between groups on reported hours per day spent sitting at follow up. Both groups did reduce the amount of time sitting with the intervention group achieving a significant reduction from 7.1 hours (SD3.5) to 5.7

hours (SD2.7) which is more in line with the average sedentary time reported in the Scottish Health Survey of 5.5 hours on weekdays and 6.1 hrs weekend days for males and 5.4 hrs weekdays and 5.9hrs weekend days for women. Sedentary behaviour is defined as any waking behaviour characterized by an energy expenditure ≤1.5 METs and a sitting or reclining posture (277). There is a desire to reduce sedentary behaviour as there has shown to be a strong association reported between the physical component of successful ageing and sedentary behaviour, which also noted a dose-response relationship, in that, less time spent in sedentary activities was associated with higher odds of successful ageing (278). Both groups reduced the amount of hours sitting with the intervention group achieving a greater significant reduction than the control group, which may have been as a result of overall positive health messaging in both groups, and is an encouraging health outcome in relation to metabolic disease risk.

Overall as reported in the last two sections both groups had increased moderate physical activity, which may also have included walking. The intervention group achieved a significant reduction of hours sitting, which, if sustained may be clinically significant, as greater levels of physical inactivity have been reported as being associated with an increased likelihood of reporting disease and disability, low functional capacities, and being socially disengaged with life (279). Changes seen in the intervention group's reduction in body weight, anthropometric and physiological parameters can, therefore, be in part attributed to the significant amount of time being less sedentary and physically more active.

In summary although the intervention group reported high levels of confidence and had increased levels of physical activity the analysis shows it was not enough to

show a significant between group difference, and although motivation was high this had not translated into significant change in increasing levels of physical activity for the intervention group. The effect in both groups of increasing levels of vigorous activity, moderate activity and walking along with the reduction in sedentary time was associated with an improvement in all physiological CVD risk factors known to be attributed to increased physical activity; weight, systolic and diastolic blood pressure, waist circumference, total cholesterol, low and high density lipids, blood glucose and CVD risk scores, with the exception of a slight increase in triglyceride levels in the control group. These findings indicate that the extra input from the counsellors did increase confidence and motivation to increase physical activity and decrease sedentary time. However, the control group was equally as motivated to become more active and were able to improve anthropometric and physiological parameters.

6.10 Participants Health Related Quality of Life Perceptions

The SF12v2 Health Related Quality of Life questionnaire was used to measure participants' reported general health status. Responses from the 12 questions are combined in two summary scores; The Physical Component Summary (PCS) and The Mental Component Summary (MCS). There was no significant difference in mean scores between the intervention and control groups through each of the domains at baseline or follow up, however, there were differences seen at individual domain levels (Table 28).

6.10.1 Participants Response and General Health Changes

The generic SF12v2 was chosen in order to analyse participant's perception pre and

post intervention and demonstrate if weight reduction had an effect on, among other parameters, general health, vitality and mental health. There were two hundred and forty six questionnaires included in the sample at baseline and two hundred and forty two analysed at follow up, as a result of non-completion or invalid response, which is not uncommon as studies have shown that unless "questionnaires are coercively administered to the target population, a 100 percent response rate is rarely achieved" (280). Reasonable explanations for non-response may well have included lack of time; lack of understanding of the question asked or genuinely over looked the question. In an attempt to minimise a non-response rate, questionnaires were sent close to date for follow up appointment and stamped addressed envelopes were included. Reminder telephone calls may have increased response however a 98.4 % return rate could be considered a good response.

Improvements in physical activity levels, dietary intake, weight reduction and physiological measurements may all have conceivably contributed to the significant increase in vitality seen in the intervention group, as the effects of these improvements are known to have a positive effect on Health related quality of life (HRQOL) and psychological health (281),

As both groups had made positive improvements to dietary intake and physical activity levels further investigation would be required to determine reasons for the decrease in physical functioning in the control group and not the intervention group. As the study was powered to detect change in body weight the number of subjects in this sample may not have sufficient statistical power to detect changes throughout all the domains.

The SF12v2 questionnaire showed a percentage of the "norm population" and HF2

sample at risk of depression (based on the standardised "normative data of a score of 50 and standard deviation of 10) (section 4.6.1). Baseline and follow up values showed the norm population to have a 20% risk; the HF2 sample risk was lower at 15% baseline and 14% at follow up, indicating an increased proportion of participant satisfaction with HRQOL in the HF2 sample, which could be attributed to the increased vitality and overall improvements seen for both groups in weight, diet and physical activity.

The summary measure in the longer SF36 form do give more reliable estimates of individuals levels of health and wellbeing because it defines more levels of health and better represents the content of health measures than the SF-12v2 (282), however, the questionnaire length being reduced by two thirds and with minimal loss of measurement precision makes it a justifiable alternative to the longer and more time consuming to administer SF36 form (282). It could be argued as to the usefulness of a health related quality of life questionnaire used in an intervention such as HF2 without a clear objective as to how the information would be followed up, the results show a change from baseline to follow up but without further investigation we can only speculate if it was the intervention that effected that change. There is a possibility that the information could be used for triaging to other services, however, this would require cut off values to determine the level of need for physical or mental health intervention (283). In summary the results from the HRQOL questionnaire have shown changes which are consistent with the improvements seen in diet, physical activity and CVD risk factors for both groups.

6.11 Participant Satisfaction with the intervention

It is important that participants' satisfaction with the intervention is high as it can affect compliance with the intervention if they are not. A review of the data showed overall participant satisfaction to be high. There were 80.1% of questionnaires returned and a high percentage of participants rated the HEALTHFORCE 2 study as a worthwhile or excellent program. This was significantly higher in the intervention group (94.5%) than the control group (93.9%) which is likely to be due to the differences in the "excellent" rating (between group difference p=0.046) as if the excellent and worthwhile responders had been combined the difference may not have been significant. Both groups reported the study as being useful (94.9%), helping them to change their diet (88.3%) and levels of physical activity (72.6%). As the questionnaires were returned anonymously there was no way to pursue non-responders for feedback.

The participant satisfaction questionnaire asked if the telephone calls and posted materials help make changes to diet and/or levels of exercise. This question was included so as to distinguish between those who had the intervention and those who had not. Those who did not receive the intervention had the option to tick a "not applicable box"; however, the limitations in self-reporting can be seen, with the disparity seen in the numbers shown in each group. It may be as a result of a proportion of participants ticking the box to say they were helped by the telephone calls and posted materials where in fact they may not have received any calls or posted materials (Table 5.19). There were many written notes on the returned questionnaires in an effort for the participant to make their feelings and perceptions of the intervention and non-intervention across. If this investigation had not been a

nested cohort valuable feasibility work could have been carried out with piloted questionnaires to improve then data collection quality and assess acceptability of the intervention.

Without further qualitative analysis the results from the participant satisfaction questionnaires are limited to descriptive statements, particularly as it is difficult to distinguish from the returned questionnaires which participants had truly had the intervention. Further research and analysis could be carried out to explore these descriptive statements.

Medical research requires standardised questionnaires of intraindividual and interindividual comparisons to maintain a particular kind of objectivity (284).It depends on decontextualising personal experience in order to make the experience comparable and transferrable independent of time and place. Questionnaires are developed to deduce complex experiences for statistical analysis which is in contrast to participants' sense of personal experience (285). Participants try to describe a precise and specific personal experience which aims to be as accurate as possible. This reduction can make it more difficult to answer the questionnaires and lead to frustration in their inability to give an exact depiction of their experience through their answers to the questionnaires (285).

6.11 Strengths and Weakness

There are a number of strengths and weaknesses arising from the HF2 investigation which warrant discussion. To the investigators knowledge an investigation such as the HF2 study has not been replicated. The novel components in the investigation were; a cohort consisting of a middle aged population having undergone CVD risk

screening, a fully powered randomised controlled trial of 16 weeks duration with the primary outcome of change in body weight and secondary outcomes to evaluate change in CVD risk factors, and using the telephone as the primary mode of delivery. One of the major strengths of the study was its ability to recruit participants from a range of socioeconomic backgrounds.

The Healthforce 1 (HF1) (50) study demonstrated that it was feasible to deliver and implement a face to face lifestyle intervention with focus on diet and physical activity in adults undergoing CVD risk screening, and the findings from the study supported the development of this investigation. The HF2 study has shown that it is possible for a fully powered randomised controlled trial to show modest changes in weight loss and modifiable CVD risk factors in both groups. The weight loss seen in the HF1 study was 1.1kg in comparison to 0.8kg in the HF2 investigation which was fully powered to detect changes in both intervention and control groups. The reason for the larger weight loss seen in the HF1 investigation (50) may have been in part due to delivery of one to one consultations rather than telephone consultations, although participant acceptability of both programmes was shown to be high. There were also comparable changes seen in waist circumference, physical activity and diet, with both studies showing increases in levels of moderate physical activity and number of daily portions of fruit and vegetables consumed. These findings demonstrate support for this type of lifestyle change intervention.

The interventions' effectiveness relied on the counsellors identifying predictors of the individuals' behaviour and gaining an understanding of the attitudes and beliefs towards that behaviour. The counsellors had to facilitate reaching a decision balance, weighing pros and cons of good versus ill health and the consequences of remaining over weight. Once established a plan to change the particular behaviour

in pursuit of behavioural goals is realised. The behaviour techniques used to help subjects to achieve the behaviour change involved goal setting, self-monitoring, feedback and reinforcement improving self-efficacy and enlisting social support.

Although the HF2 intervention was not successful in achieving statistically significant weight loss, there were many positive outcomes. There was a significant percentage weight loss in the intervention group at a level which has shown to be clinically meaningful (section 6.4) in patients with type2 diabetes (10). There were significant improvements in anthropometric modifiable risk factors (section 6.5), shown in the intervention group notably a reduction in waist circumference (section 5.3.1), total cholesterol and low density lipoproteins, (section 5.3.2.3) all of which contribute to increased CVD risk. The study was shown to be acceptable with good participation satisfaction feedback for both intervention and control groups, with 94.5% in the intervention group rating the program as "worthwhile or excellent".

The methodology used to determine weight loss in the HF2 investigation was robust with the inclusion of waist circumference as a measure of abdominal obesity and is strength of the study. Other means of measuring weight loss can include skin fold caliper measurement which is considered an accurate, effective, practical and repeatable method of measuring body fat, as long as the measures are in the same spot each time. It does require to be carried out by trained experienced observers as it can be quite susceptible to measurement error. The gold standard methods to measure body fat are hydrostatic weighing and Dual Energy X-ray Absorptiometry known as DEXA which are very accurate but expensive but would have not been

practical to incorporate into the HF2 study. Both these measures although considered more accurate does add to participant burden.

Reliance on food frequency questionnaires for epidemiological studies has been the foundation of assessing dietary intake for several years (286) and although these assessment tools are subject to test for reliability and validity, evidence has shown that when individuals are asked to recall diet in the very recent past, their memory is reasonably accurate; however, after only a few days, memory of diet weakens (286). Assessment of food intake is potentially subject to many sources of both random and systematic error. Recall ability and psychological characteristics of individuals are known to influence dietary reporting, such as reporting behaviour perceived as socially desirable rather than accurate (287).

Future interventions could see incorporating technological devices such as personal digital assistants with or without a camera with specifically designed dietary software to record data immediately after food consumption, scrolling down a list of food groups then selecting a specific food and portions (288) , and relatively cheaper recently developed 24hr online dietary software such as INTAKE24 (289) and myfood24 (290) . It would not have been possible to incorporate these methods in the HF2 investigation due to cost and would have necessitated a feasibility study to assess participant compliance and acceptability, when resources and time were limited in this investigation.

According to the principle developed by Hall and colleagues (291) a 1% BMI reduction across the UK population, equivalent to a weight loss of 1 kg, would avoid up to 179,000 – 202,000 cases of type2 diabetes, 122,000 cardio vascular diseases, and 32,000 – 33, 000 incidents of cancer with a gain of about 3 million QALYs over

20 years (291), a net 20 kcal per day reduction would be required to be sustained for 3 years to enable this reduction in the prevalence of NCD's. In addition to compromising the populations' healthy, productive life span, by 2030, these increases in obesity-related diseases were projected to add to health-care costs by £1.9 –2 billion a year in the UK (291). The HF2 intervention did not achieve a 1kg weight loss but did achieve a 0.9kg weight reduction which was a significant amount from baseline to follow-up and is encouraging considering the short duration of the study.

6.12 Future Work

Both groups were successful in achieving weight loss and significantly improving a number of CVD risk factors, indicating that the HF2 intervention and the brief (usual care) advice were effective at initiating behaviour change. What remains to be seen is if the change could be sustained over a period of time. Improvements were seen in dietary intake and levels of physical activity, however, reporting of intake and physical activity were self-reported which can be subject to bias. Future weight loss intervention studies could incorporate the use of smart phone technology to include existing applications which record dietary and physical activity data in real time, as currently used in commercial trials, where data can be captured on smart phones, transmitted to a central server and analysed by the investigating team. Opportunities to incorporate new applications could be explored for inclusion in future feasibility studies.

Methods used to measure alcohol intake in future weight loss interventions could include the AUDIT (The Alcohol Use Disorders Identification Test) tool (292)), the

addition of this measurement would enable more accurate participant recall, and enable a more specific measure of the various types of alcoholic drinks consumed and the calorific content.

Although both intervention and control groups significantly reduced their CVD risk *scores,* these results were not defined by gender, or SIMD something which could be explored in future work, particularly as the CVD risk perception questionnaire results showed that women perceived their risk to be lower than men's. These results highlight the need to explore CVD risk perception in women to investigate possible reasons why they did not recognize the increased level of risk and why they felt their risk of CVD is a lesser threat to their health than it is to men. The CVD risk perception questionnaire was designed purposely for the HF2 study as the investigator was unable to source an appropriate validated questionnaire specific to the question asked. A proposal for designing and developing a CVD risk perception measurement tool which could initiate discussion on an individual's level of risk would also be a valuable contribution to future interventions investigating CVD risk perception.

6.13 Conclusons

The UK's fall in Cardiovascular Disease (CVD) mortality can be attributed to increased public understanding of risk factors, government policies to enable healthier lifestyles and improved treatment and prevention services. Screening is one such preventative measure if followed up. The aim of the (HF2) investigation was to assess the outcome of a brief lifestyle intervention versus a multiple contact, minimal cost intervention on reducing body weight and modifiable CVD risk factors

in healthy volunteers following cardio-vascular risk screening, in order to determine what level of intervention input would affect initiation and maintenance of lifestyle change, body weight and cardio-vascular risk factors.

Screening a healthy population for the HF2 investigation, in a research setting, for risk of CVD provided a platform and opportunity to discuss individual risk and provide lifestyle advice. The target age group for this investigation of those over 40years old provided an opportunity to target a middle aged group at a time in the life course when they may be more likely to weigh up the benefits of future good health against the burden of ill health. The HF2 investigation offered an opportunity to attempt to bring about behaviour change to a group who were voluntarily presenting for risk screening so may by definition already have been thinking about their health and more receptive to lifestyle advice.

There is sufficient scientific evidence to indicate that lifestyle modification interventions which include nutritional advice, increased physical activity, moderate alcohol intake and smoking cessation can offer a successful approach for the prevention of heart disease and stroke.

The outcome of the HF2 investigation showed there was no difference between the multiple contact lifestyle change intervention versus the brief lifestyle change intervention (usual care). There were differences seen in the PP analysis, however, there was no statistically significant difference seen between the intervention and the control group in the ITT analysis in terms of the primary outcome weight loss, lending support for instigating brief interventions and the concept of the “teachable moment”. The intervention did, however, show that a lifestyle change intervention using the HF2 methodology can result in a modest weight reduction and show

statistically significant improvements in physiological markers of CVD risk factors such as waist measurement, diastolic blood pressure, total cholesterol and low density lipoproteins. As there was little difference seen between the multiple contact intervention group and the usual care group it is difficult to determine which specific elements were successful in the intervention which brought about the change. There was little difference in the primary outcome or secondary outcomes. Perhaps it was the case that both groups were motivated by the CVD risk screening, and that highlighting the future health risks in this age group was enough to motivate both groups equally to reduce weight, improve diet and increase activity, or that the usual care group were more health conscious, and as they were not going to receive any further input from baseline to follow up they decided to take it upon themselves to be more proactive. These are speculative reasons and not measured and as so means it is not possible to draw any firm conclusions as to the reason why the intervention was not successful in promoting a significant weight loss in the intervention group compared to the usual care group.

The results from the investigation will contribute to the existing knowledge base for behaviour change intervention studies, by showing that a single brief lifestyle intervention delivered in a screening setting was just as effective in affecting behaviour change as a multiple contact intervention and enhance the evidence base on potentially cost effective strategies to encourage lifestyle change, in order to reduce the prevalence of obesity and CVD's.

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Appendices

Appendix A.

Search alerts were set in order to ensure notification of new literature as it was published.

Alert Name	Search Terms	Alert Frequency
Scopus	Heart Disease prevention physical activity Heart Disease prevention weight loss Heart Disease prevention and brief interventions	Daily
BioMed Central	Books, Journals and Information Health Services Research Public Health Nursing Physiology Psychology Medical Research Methodology	Received as published
Obesity Knowledge Update		Weekly
International Association for the Study of Obesity (IASO)		Weekly News Brief

Appendix B

Each publication was considered by reviewing the title and abstract and included or excluded from the search as determined by a set criterion.

Criteria for exclusion into Review
Study Design: Study duration =>4months Population: Babies, Infants Studies written in language other than English.

Criteria for inclusion into Review
Study Design: Randomised controlled trials, intervention studies, prevalence surveys, case studies, systematic reviews and meta-analysis, cross-sectional observational. Relevant policy documents, government reports and commentary from Public Health Practitioners and other relevant professionals were also included.
Population: Male/female, middle age, over 40's, overweight, obese.
Article Themes: Health behaviour models/theory, beliefs attitudes to health related behaviour, behaviour techniques, the telephone as method to deliver health intervention, barriers to behaviour change, strategies for improving diet/physical activity, screening setting as opportunity to introduce behavior intervention, perceptions of CVD risk.
No geographical limitations.

Appendix C

The assessment of methodological quality of the studies included in the review is based on a check list for critical appraisal of studies. (19)

Assessment of Methodological Quality of Studies
Are the aims and objectives clearly defined? Poorly defined aims and objectives may suggest that a research question was not initially determined resulting in a poorly defined study.
What are the sampling methods? Was the sampling strategy clearly described and justified? Was the sampling strategy theoretically comprehensive enough to ensure generalisability of the findings or were they restricted to a highly selective group of individuals. This is important for the validity of the findings.
What is the justification for the sample size? Studies should be large enough to represent what is going on and to detect important effects.
Are measurements likely to be reliable and valid? Studies of high quality will discuss how reliability and validity were assessed. If they have not been described then the reader must consider the possibility that there could be measurement errors and decide whether these errors could be important. How was the data collected? Could the evidence (physiological, biological, interview transcripts, recordings, documentary analysis, etc) be inspected independently by others: if relevant, could the process of transcription and calibration of equipment be independently inspected?

Where there any untoward events during the course of the study?

Missing data can allow introduction of bias, and if problems occur during the course of the study this could lead to changes in the study design which can cause more problems and indicates a poor quality study.

Do the findings fit?

The size of each effect described in the findings is scrutinized to discover its importance. Careful scrutiny for evidence of bias and confounding must also be carried out. Are the findings plausible? Do they make biological sense do they fit with what is already known about the topic. How do the findings compare with other studies? The findings from a single publication must be considered with a balanced overview with findings from all other reported studies.

Assessment of Methodological Quality of Studies

Are the aims and objectives clearly defined?

Poorly defined aims and objectives may suggest that a research question was not initially determined resulting in a poorly defined study.

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Appendix D

THE TASCFORCE PROJECT

Tayside **Sc**reening **for** risk of **C**ardiac **E**vents

Participant Information Leaflet No 1 (PIL 1 Version 6)

Cardiovascular Risk assessment by BNP

You have been sent this information sheet because you have expressed an interest in taking part in the TASCFORCE Project. We aim to enroll 5,000 Tayside and Fife men and women into this study. Since you are aged 40 years or over and are not known to have diabetes, hypertension, stroke, heart or blood vessel disease, you may be suitable to take part. Before you decide whether to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

We have also attached an information leaflet on a sub-study we are carrying out; HEALTHFORCE 2. This is our second project looking at the best ways to deliver lifestyle advice. If you wish to take part and are eligible, we will be delighted to discuss this further with you at your TASCFORCE screening visit.

PURPOSE OF THE TASCFORCE PROJECT

Heart attack and stroke are still amongst the most common causes of illness and death in Scotland, despite major advances in preventive medicine. National guidelines are in place to assess whether an individual is at risk of heart and blood vessel disease, and thus requires treatment. We believe, however, that some people may still be at risk, but that the current methods of assessments fail to detect this. The project has been designed to identify these people, to screen for early signs of heart disease and to find out how effective new screening techniques are in predicting the risk of heart disease so that it can be prevented or treated at an early stage.

The project will be carried forward in two stages:

1. Assessment of cardiovascular (heart and blood vessel) risk.

2. Screening for early signs of cardiovascular disease by Magnetic Resonance Imaging (MRI, heart and blood vessel scan) in those found to be at risk.

At the first stage of the project, we wish to identify those who may be at, as yet undetected, cardiovascular risk by measuring a blood chemical called BNP. The level of BNP in the blood shows how well the heart is working and helps us to assess risk. This information sheet tells you about this first stage of the TASCFORCE project. If you are selected to continue to a further stage a separate information sheet and explanation will be given at the time before asking for your consent for further participation.

How will you know that I may be at risk?

Your blood pressure, weight, height, and levels of blood glucose and cholesterol will be measured. These measurements, along with whether you smoke and have a family history of heart or stroke disease will be used to calculate your risk of developing heart disease. If you are found to be at risk using the standard methods of assessment, we will advise you and discuss what next to do to ensure you receive treatment. If you do not seem to be at risk using standard methods, then we will take a blood sample to measure a substance called BNP which measures risk.

What will I be required to do?

You will be asked to attend for one visit to Ninewells Hospital, or to your GP's surgery, or other suitable place. You will have the opportunity to discuss the study and to receive answers to any questions you may have before being asked to sign a form consenting to take part. This visit is to find out if you are suitable to take part in the study and to assess your risk of developing heart disease.

The study nurse will:

- Ask you about your present and past illnesses and what medicines you are taking.
- Ask you whether you smoke and whether any members of your family have had heart disease.
- Carry out an ECG (this is a tracing of your heart activity).
- Measure your blood pressure, weight, height and waist circumference.
- Take some blood (20 ml - about 4 teaspoons) for various tests. This blood will be used to check your blood glucose and cholesterol level, and your level of BNP. These tests will be done right away at the bedside. The rest of the blood will be stored for future research into heart and blood vessel disease as part of a Bio-bank in the Institute of Cardiovascular Research.
- Give you advice and leaflets on how to change your lifestyle to reduce your risks.
- Take a separate blood sample 9ml for genetic study (optional) if you agree to it. A separate information sheet is attached for the genetic sub-study.

If you need treatment under the current recommendations, we will advise you of this, and arrange for you to see your General Practitioner.

If your level of BNP is raised you will be offered a MRI scan of your heart and blood vessels. This will be explained to you at the time and a separate information sheet will be given to you before asking for your consent. If your level of BNP is low then you will be informed, your participation will be gratefully acknowledged but will not be required beyond this first visit.

We will ask your permission to allow us to receive from or pass on any relevant information to your GP for the duration of the study and for a period up to twenty years beyond the study end. We will ask your permission to register your name with the Scottish Office so that we may receive information on any hospital admissions you may have and their diagnoses and to be notified in the unlikely event of your death for a period of up to 20 years. We would also ask you to allow us to contact you at 2, 5, and 10 years after the study ends to find out if you have had any health problems relating to your heart or blood vessels. This will allow us to assess how

effective our screening techniques are in predicting and in preventing heart and blood vessel disease and help increase our understanding of these diseases.

Will I be given the results of any tests that you do?

If you have given a blood sample for DNA, neither you nor your GP will be given the result. You will be informed of your blood pressure, cholesterol levels, and whether your BNP is high or low.

What are the potential advantages of taking part in the study?

You will have the opportunity to reduce your cardiovascular risk by receiving lifestyle management advice and leaflets on any modifiable risks that you may have. If from any of the tests that we do, we feel you should have further investigation, the results will be sent to your GP so you can be treated according to current clinical practice. There is no guaranteed benefit from taking part in the study but your participation contributes to medical science and possible future benefits.

What are the potential disadvantages of taking part in the study?

Blood sampling: Taking blood can be briefly uncomfortable and can on occasion cause some bruising.

How will my information be stored?

Any information we obtain from you and your health records will remain strictly confidential. Information will be stored securely under conditions in keeping with the Data Protection Act 1998. To ensure confidentiality we will allocate a code (not your name) to your records and to your blood samples. We will keep your personal details (name and address) separate from the information collected but linked by your code. Only individuals directly involved with the study will have access to this information. Reports or publications of research findings will not contain information through which you can be identified. We may be required to allow regulatory authorities, who ensure that research is being carried out in the correct manner, to inspect your records but they will not have access to your name or address.

What if anything goes wrong?

Indemnity is provided by the NHS. The University of Dundee covers any non-negligent harm that occurs due to the design of the clinical trial. Any harm that may occur by the use of medication is covered by the manufacturer under the Consumer Protection Act.

What are my rights?

Participation in this study is voluntary and you are free to withdraw from the study at any time without having to give a reason. This will not affect your medical care. If you decide to take part you will be given this Information Sheet to keep along with a copy of the Consent Form that you would be required to sign. If you should ever have any concerns about this study or the way it has been carried out, you should

contact:

Dr Roberta Littleford, Trial Manager	01382 633963
Professor Jill JF Belch, Principal Investigator	01382 632457

The Tayside Committee on Medical Research Ethics has examined this proposal and has raised no objections from the point of view of medical ethics.

Thank you for taking time to read this information sheet.

One of the study nurses will telephone you in the next week to answer any questions that you may have and to make an appointment for you if you decide to take part.

Roberta Littleford

Trial Manager

The TASCFORCE Project
The Institute of Cardiovascular Research
Vascular & Inflammatory Diseases Unit
Ninewells Hospital & Medical School, Dundee DD1 9SY
Telephone 01382 633963
E- mail: tascforce@dundee.ac.uk

Appendix E

Patient Information Leaflet for HEALTHFORCE 2 Study Part of the TASCFORCE PROJECT

This study is being undertaken in part fulfillment of an educational project. My name is Janice Rowland and I am a Clinical Research Nurse on the TASCFORCE Project at the University of Dundee. I am required to undertake a project as part of my thesis and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it and secondly what it would involve if you agreed to take part. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including friends and family. I will do my best to explain the project to you and provide you with any further information you may ask now or later.

What is the purpose of HEALTHFORCE 2?

In 2009, our first HEALTHFORCE project looked at how useful it was to use multiple one to one contacts to implement a lifestyle intervention programme, helping people to meet their own weight loss, diet and exercise goals. The vast majority[1] of the participants' goals were achieved but the costs may prove to be too expensive where there are limited funds available.

The participants in the first HEALTHFORCE project had also participated in the TASCFORCE project.

TASCFORCE has been screening people for the past 3 years. In that time we have heard from previous study participants that as a result of the information they were given at their screening visit they had decided to make some changes to their lifestyle i.e.; stopped smoking, weight loss or taken up more exercise.

Therefore, HEALTHFORCE 2 is designed to compare the methods used in TASCFORCE with the new HEALTHFORCE 2 study.

Who will be asked to take part in the HEALTHFORCE 2 study?

We know that increased weight can result in a person being at higher risk for developing heart disease. Increasing weight can also lead to other health problems such as type 2diabetes and high blood pressure. The Body Mass Index (BMI) is a number calculated from an individual's weight and height that is used to determine whether a person is within, or outside of, a normal weight range. If your BMI is found to be 25kg/m^2 or more then you will be invited to take part in the HEALTHFORCE 2 Study.

What will happen if I take part in the HEALTHFORCE 2 Study?

This new design will mean half the people who take part will be given lifestyle advice alone and the other half will be given additional support and information over a period of four months. Both groups return for a mini-screening visit after 4 months. We hope to recruit 264 people onto this study.

If you are eligible and decide to take part in this study your allocation to either group will be completely random. Just like throwing a dice.

On your first TASCFORCE Visit you will be asked to give written consent for both the TASCFORCE Project and the HEALTHFORCE 2 study. Your BMI will be calculated during the screening visit and it will be at that point you will know if you are eligible to take part. No additional tests are carried out at this visit if you choose to take part.

If you do take part, two to three weeks after your TASCFORCE screening visit you will be sent a questionnaire which is in three sections, which asks you about your general health, current eating habits and exercise patterns. When you return your questionnaire, you will be randomly allocated to either of the two groups.

From this point in the study I will not know your group allocation, this will allow me to analyze the study's results without prior knowledge of which group you or the other participants are in. The researchers involved in the first HEALTHFORCE project will be involved in this part of the study. Therefore, the letters you will receive will be from Dr Angela Craigie and the telephone calls will be from one of Dr Craigie's trained lifestyle counsellors.

If you are allocated to Group 1, you will receive a letter that will inform you that we will contact you again in four months to arrange your final study assessment at the Clinical Research Centre at Ninewells Hospital.

If you are allocated to Group 2 you will be informed that you will receive a call from your lifestyle counsellor within a week. During this call you can establish a convenient schedule for your other calls. The letter will also advise you of the information packs and the items that will be enclosed that may help you achieve your goals. The first pack will include information on physical activity and a pedometer (a small gadget that slips onto your waistband that counts the number of steps you take each day). Physical activity will be the first topic discussed during your call with your lifestyle counsellors.

One week before your next three scheduled calls you will receive a pack, the contents of which will be the topic for your conversation with your lifestyle counsellors. Over the next three months you will receive information on fruit and vegetables, weight loss and ways to avoid weight gain. With these packs you will receive an individual vegetable steamer, apple corer/slicer, waist measuring tape and an alcohol and calorie counter wheel.

After four months both groups will receive a letter to attend your final assessment. Included, will be three questionnaires, the same as you have just completed. We will ask you to return them prior to your appointment date. This visit should take approximately 30 to 40 minutes and will involve you having a blood sample taken (4mls, less than a teaspoon) to measure your cholesterol and blood glucose levels, and we will also check your blood pressure. We will take your weight, height and waist measurements and calculate your body mass index (BMI). This will enable us to assess your weight loss and cardiovascular risk compared to the results from your first visit. You will be given these results at the visit, and given the opportunity to discuss them with a member of the research team.

The visits will take place in the Clinical Research Centre at Ninewells Hospital, we will give you directions before your visit.

We will also give both groups simple questionnaires to complete which will enable us to compare both group's thoughts and feelings towards their health, diet exercise and risk of developing heart disease.

Do I have to take part?

No. It is up to you whether you take part in the HEALTHFORCE 2 study. Whether you choose to or not will not affect you taking part in the main TASCFORCE study.

What are the Disadvantages of taking part?

The study does potentially involve you giving up some of your free time to fill in a few questionnaires, post them back, read the information packs and take four calls from your lifestyle counsellor. At the four month follow visit at Ninewells Hospital up a small sample of blood will be taken (less than a teaspoon) to measure your cholesterol and blood sugar levels.

What are the Advantages of Taking Part?

You will have the opportunity to reduce your cardiovascular risk by receiving lifestyle management advice if you take part in the main TASCFORCE screening project. In addition to this if you are asked to take part in the telephone follow-up phase you will receive continued support and advice on how to reduce weight and increase you physical activity levels. You will also have the benefit of seeing for yourself if you have made any changes to your cardiovascular risk in a four month period. There is no guarantee that you will benefit from taking part in the study but your participation contributes to medical science and possible future benefits.

How will my information be stored?

Any information we obtain from you and your health records will remain strictly confidential. Information will be stored securely under conditions in keeping with the Data Protection Act 1998. To ensure confidentiality we will allocate a code (not your name) to your records and to your blood samples. We will keep your personal details (name and address) separate from the information collected but linked by your code. Only individuals directly involved with the study will have access to this information. Reports or publications of research findings will not contain information through which you can be identified. We may be required to allow regulatory authorities, who ensure that research is being carried out in the correct manner, to inspect your records but they will not have access to your name or address.

What if anything goes wrong?

Indemnity is provided by the NHS. The University of Dundee covers any non-negligent harm that occurs due to the design of the clinical trial. Any harm that may occur by the use of medication is covered by the manufacturer under the Consumer Protection Act.

What are my rights?

Participation in this study is voluntary and you are free to withdraw from the study at any time without having to give a reason. This will not affect your medical care. If you decide to take part you will be given this Information leaflet to keep along with a copy of the Consent Form that you would be required to sign. If you should ever have any concerns about this study or the way it has been carried out, you should contact:

Dr Roberta Littleford, Trial Manager 01382 633963
Professor Jill JF Belch, Principal Investigator 01382 632457

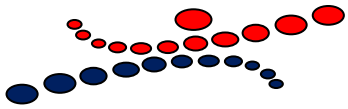
The Tayside Committee on Medical Research Ethics has examined this proposal and has raised no objections from the point of view of medical ethics.

Thank you for taking time to read this information leaflet.

Janice Rowland
Clinical Research Nurse
The TASCFORCE Project
The Institute of Cardiovascular Research
Vascular & Inflammatory Diseases Unit
Ninewells Hospital & Medical School, Dundee DD1 9SY
Telephone 01382 633963
e-mail: tascforce@dundee.ac.uk

1. Craigie A et al. Healthforce: *A feasibility study of a lifestyle management programme for cardiovascular risk screening participants.* Proceedings of the Nutrition Society (in press).

Appendix F



Risk perception Questionnaire

Risk Perception Question (pre-screening)

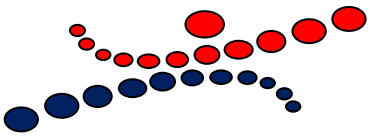
Please take the time to complete this question you will be asked the same question at the end of the Screening Visit.

Compared with a person of your own age and sex, how would you rate your risk of having a heart attack or stroke in the next 10 years?

Please tick one of the boxes below:

Much lower than average	
Lower than average	
Average	
Higher than average	
Much higher than average	

Thank you for taking the time to complete this questionnaire.



Risk Perception Question (post-screening)

We hope you found your screening informative, and are interested to know if there has been any change in how you rate your level of risk since before the screening.

Compared with a person of your own age and sex, how would you rate your risk of having a heart attack or stroke in the next 10 years?

Please tick one of the boxes below:

Much lower than average	
Lower than average	
Average	
Higher than average	
Much higher than average	

Thank you for taking the time to complete this questionnaire.

Appendix H

YOUR GENERAL HEALTH

1. In general, would you say your health is?

Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor ☐

2. The following questions are about activities you might do during <u>a typical day</u>. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
b. Climbing several flights of stairs	☐	☐	☐

3. During the <u>PAST 4 WEEKS</u>, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your <u>PHYSICAL HEALTH</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	☐	☐	☐	☐	☐
b. Were limited in the kind of work or other activities	☐	☐	☐	☐	☐

4. During the <u>PAST 4 WEEKS</u>, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of <u>any EMOTIONAL PROBLEMS</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	☐	☐	☐	☐	☐
b. Did work or activities less carefully than usual	☐	☐	☐	☐	☐

5. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely ☐

6. These questions are about how you feel and how things have been with you DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the PAST 4 WEEKS...

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a.	Have you felt calm and peaceful?	☐	☐	☐	☐	☐
b.	Did you have a lot of energy?	☐	☐	☐	☐	☐
c.	Have you felt downhearted and depressed?	☐	☐	☐	☐	☐

7. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. Thinking back to when you were 21 years old, how does your current weight compare to what you weighed then?

I weigh less now	I weigh about the same now	I weigh more now	Don't know / not sure
☐	☐	☐	☐

9. Have you made any previous attempts at weight loss? Yes ☐ No ☐

If yes:
Have you followed any particular weight loss programmes? If so please list:

_____

_____

Were you successful with any of these? Yes ☐ No ☐

If successful, please specify which weight loss programme you were following?

_____

_____

YOUR UNDERSTANDING OF CARDIOVASCULAR/STROKE RISK FACTORS

1. **What do YOU PERSONALLY think are the main factors that might increase or decrease a person's chance of developing cardiovascular disease or a stroke? (list as many as you believe do increase or reduce risk of the disease)**

INCREASE RISK	DECREASE RISK
……	……
……	……
……	……
……	……
……	……
……	……

Appendix I

Have you eaten any of the following foods in the last 24 hours?

PLEASE "X" THE NUMBER OF PORTIONS OF FOODS EATEN FOR EVERY ROW FOR EXAMPLE:

	NUMBER OF PORTIONS				
	0	**1**	**2**	**3**	**4+**
Fruit as a dessert	☐	☒	☐	☐	☐

	NUMBER OF PORTIONS				
	0	1	2	3	4+
Breakfast cereal	☐	☐	☐	☐	☐
Fruit for breakfast, e.g. on cereal	☐	☐	☐	☐	☐
Crisps	☐	☐	☐	☐	☐
Fruit as a between meal snack	☐	☐	☐	☐	☐
A glass of pure, unsweetened fruit juice (not squashes or fruit drink)	☐	☐	☐	☐	☐
Fruit as a starter to a meal	☐	☐	☐	☐	☐
A baked potato	☐	☐	☐	☐	☐
A bowlful of home-made style vegetable soup	☐	☐	☐	☐	☐
Portions of vegetables with main meals (include baked beans and pulses as vegetables but not potatoes)	☐	☐	☐	☐	☐
Any type of meat	☐	☐	☐	☐	☐
A vegetable based meal	☐	☐	☐	☐	☐
Any type of fish	☐	☐	☐	☐	☐
A bowlful of salad	☐	☐	☐	☐	☐
Fruit as a dessert	☐	☐	☐	☐	☐

Appendix J

Your Eating Habits:

Please answer the following questions about your diet by ticking the box which best describes your food intake.

1

About how many times **a week** do you eat a serving of the following foods?				
	Less than 1 a week	1-2 a week	3-5 a week	6 or more a week
Cheese (any except cottage)				
Beefburgers or sausages				
Beef, pork or lamb (if vegetarian include nuts)				
Bacon, meat pies, processed meat (including ham)				

score

2

About how many times **a week** do you eat a serving of the following foods?				
	Less than 1 a week	1-2 a week	3-5 a week	6 or more a week
Chicken or turkey				
Fish (**NOT** fried or in batter)				
Any fried food; fried fish, chips, cooked breakfast, samosas				
Cakes, pies, puddings, pastries				
Biscuits, chocolate, or crisps				

score

3

How much milk, and of what kind, do you yourself typically use **in a day** e.g. in cereal, tea, coffee, etc?				
	Less than quarter pint	About a quarter pint	About a half pint	1 pint or more
Full cream				
Semi skimmed				
1% milk				
Skimmed/None				

score

4

What sort of fat do you use? (choose one on each line)					
	Butter, dripping, lard, solid cooking fat (White cap, Cookeen)	Hard or soft margarine, White Flora, Dairy blends (Clover, Willow, Golden Crown), half fat butter	Polyunsaturated/ sunflower margarine or low fat spread (Gold Outline, Shape, Flora Extra Light, Delight)	Pure vegetable oil (e.g. sunflower, soya, corn, peanut, olive)	No fat used
On bread and vegetables?					
For Frying?					
For baking or cooking?					

Total score	

5

About how many pats or rounded teaspoons of margarine, butter or other spread do you usually use **in a day**, for example on bread, sandwiches, toast, potatoes, or vegetables? (enter number in box)	
Butter or margarine**:**	
Low fat spread:	

6

About how many times **a week** do you have a bowl of breakfast cereal or porridge? What kind do you have most often? (choose only one if possible)				
	Less than 1 a week	1-2 a week	3-5 a week	6 or more a week
Sugar type: Frosties, Coco Pops, Ricicles, Sugar Puffs				
Porridge or Ready Brek **Wheat type**: Shredded Wheat, Weetabix, Puffed Wheat, Fruit 'n Fibre, Nutri grain **Muesli type**: Alpen, Jordan's				
Bran type: All Bran, Bran Flakes, Sultana Bran,				

7

On a typical day, about how many pieces of bread or rolls do you eat? Are they usually white, brown or wholemeal? (choose only one if possible)				
	Less than 1 a day	1-2 a day	3-4 a day	5 or more a day
White bread				
Brown or granary bread				
Wholemeal bread or 2 slices crispbread				

score	

8

About how many times **a week** do you eat a serving of the following foods? (choose only one if possible)				
	Less than 1 a week	1-2 a week	3-5 a week	6 or more a week
Pasta or rice				
Potatoes				
Peas				
Beans (baked, tinned, dried) or lentils				
Other vegetables not already included (any)				
Fruit (fresh, frozen or canned)				

Total score		

9.

Can you tell me how often, on average, you drink sugary drinks? (note – this does **NOT** include diet or low-calorie drinks or fresh fruit juice)								
6 or more a day	4 / 5 times a day	2 / 3 times a day	Once a day	5 / 6 times a week	2 - 4 times a week	Once a week	1 - 3 times a month	Less often / never
☐	☐	☐	☐	☐	☐	☐	☐	☐

10. **How many rounded teaspoons of sugar do you have on a usual day e.g. in tea or coffee or on cereals?**

☐ Rounded teaspoons

11. **How often do you have a drink containing alcohol?**

Never ☐

Monthly or less ☐

2 to 4 times a month ☐

2 to 3 times a week ☐

4 or more times a week ☐

12. **How many drinks containing alcohol do you have on a typical day when you are drinking?**

1 or 2 ☐

3 or 4 ☐

5 or 6 ☐

7 to 9 ☐

10 or more ☐

13. **Which of the following describes your smoking status?**

☐ Current Smoker How many cigarettes would you smoke per day ☐☐

☐ Ex Smoker

☐ Non Smoker

The following questions ask your views about diet:

1 Are you currently thinking about eating a healthier diet in the future?

Yes ☐ **No** ☐ If no, go to question 3

2a If **Yes** – When do you plan to begin eating a healthier diet?

Within the next month	Within the next 6 months	Yet to decide
☐	☐	☐

2b How **confident** are you that you will stick to this plan?

Very confident	Somewhat confident	Mildly confident	Not at all confident
☐	☐	☐	☐

3 Have you ever made a deliberate effort to improve your diet? **Yes** ☐ **No** ☐

4a If **Yes** – Are you still eating a healthy diet? **Yes** ☐ **No** ☐

4b If **Yes** – Have you been able to maintain eating a healthy diet for 6 months or more? **Yes** ☐ **No** ☐

END OF THE QUESTIONNAIRE

Thank you for your time and effort

Appendix K

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (IPAQ)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**.

Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your housework, gardening, getting from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**.

Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**.

Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or tennis? Do not include walking.

_____ **days per week**

☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Please answer the following questions about increasing the amount of physical activity that you do:

1 Are you currently thinking about increasing the amount of physical activity that you do? **Yes** ☐ **No** ☐ If no, go to question 3

2a If **Yes** – When do you plan to begin doing more physical activity?

Within the next month	Within the next 6 months	Yet to decide
☐	☐	☐

2b How **confident** are you that you will stick to this plan?

Very confident	Somewhat confident	Mildly confident	Not at all confident
☐	☐	☐	☐

3 Have you ever made a deliberate effort to increase the amount of physical activity that you do? **Yes** ☐ **No** ☐

4a If **Yes** – Are you still doing more physical activity? **Yes** ☐ **No** ☐

4b If **Yes** – Have you been able to maintain this increased amount of physical activity for 6 months or more? **Yes** ☐ **No** ☐

Appendix L

Demogaphic Questionnaire

Thank you for taking part in this study. The following questionnaire asks some questions about you. There are no right and wrong answers and the answers you give will be kept completely confidential. If there are any questions you would prefer not to answer, please leave them blank. Otherwise please complete the questionnaire as fully and honestly as you can (mark X in the box indicating your response).

1. How would you describe your marital status?

Single ☐

Married/cohabiting ☐

Widowed/separated/divorced ☐

2. Which of the following ethnic groups do you fall into?

White ☐ Chinese ☐

Mixed ☐ Black or Black British ☐

Asian or Asian British ☐ Other ethnic group ☐

Do not wish to complete ☐

3. Educational Attainment

What is the highest educational qualification you have obtained?

Primary school ☐

Secondary school ☐

Other professional/ technical qualification or diploma after leaving school ☐

University degree ☐

Post-graduate degree (eg Masters or PhD) ☐

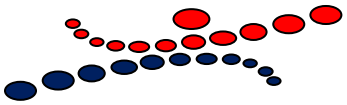
4. How would you describe your employment status? (Please tick only one)

Retired ☐ Unemployed ☐

Employed full-time	☐	Employed part-time	☐
Student full-time	☐	Student part-time	☐

Other (please specify)……

Appendix M



E-mail: a.craigie@dundee.ac.uk
Tel: 01382 496788

Date

RE: HEALTHFORCE 2 STUDY

Dear

Thank you for completing and returning the questionnaires sent to you as part of the HEALTHFORCE 2 Study.

You have now been randomly selected to **GROUP 2** in the study.

This means that in four months time you will receive your final assessment appointment letter. Included, will be three questionnaires, the same as you have just completed. We will ask you to return them prior to your appointment date. This visit should take approximately 30 to 40 minutes and will involve you having a blood sample taken to measure your cholesterol and blood glucose levels, and check your blood pressure. We will take your weight, height and waist measurements and calculate your body mass index (BMI). This will enable us to assess your weight loss and cardiovascular risk compared to the results from your first visit. You will be given these results at the visit, and given the opportunity to discuss them with a member of the research team.

If you have any questions about TASCFORCE or HEALTHFORCE 2 please contact Dr Roberta Littleford, our trial manager on 01382 633963.

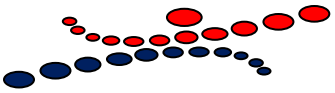
Thank you for your assistance in this part of the study, your participation is valuable and will help us with our research.

Yours sincerely

Dr Angela Craigie
Centre for Public Health Nutrition Research

Division of Clinical & Population Sciences & Education (CPSE)

Appendix N



E-mail:
a.craigie@dundee.ac.uk
Tel: 01382 496788

Date

RE: HEALTHFORCE 2 STUDY

Dear

Thank you for completing and returning the questionnaires sent to you as part of the HEALTHFORCE 2 Study.

You have now been randomly selected to **GROUP 1** in the study.

This means that you will receive a call from the research team within the next week. This will be the first of your four calls. At this time we will establish a convenient schedule for your other calls.

Each month for the next three months you will receive lifestyle information packs and a few items that may help you achieve your goals. This will include; a pedometer (a small gadget that slips onto your waistband that counts the number of steps you take each day), an individual vegetable steamer, apple corer/slicer, waist measuring tape and an alcohol and calorie counter wheel. One week before your scheduled call you will receive a pack, the contents of which will be the topic for your conversation with your lifestyle counsellor at the next call. A diagram below illustrates this process, you could use this to note down the dates and time of the scheduled calls.

Your first information pack is enclosed with a pedometer (with instructions). The topic this month is physical activity. If you require any additional help with the information please do not hesitate to contact us.

In four months time you will receive your final assessment appointment letter. Included, will be three questionnaires, the same as you have just completed. We will ask you to return them prior to your appointment date. This visit should take approximately 30 to 40 minutes and will involve you having a blood sample taken to measure your cholesterol and blood glucose levels, and check your blood pressure. We will take your weight, height and waist measurements and calculate your body mass index (BMI). This will enable us to assess your weight loss and cardiovascular risk compared to the results from your first visit. You will be given these results at the visit, and given the opportunity to discuss them with a member of the research team.

This will enable us to assess your weight loss and cardiovascular risk compared to the results from your first visit. You will be given these results at the visit, and given the opportunity to discuss them with a member of the research team.

If you have any questions about TASCFORCE or HEALTHFORCE 2 please contact Dr Roberta Littleford, our trial manager on 01382 633963.

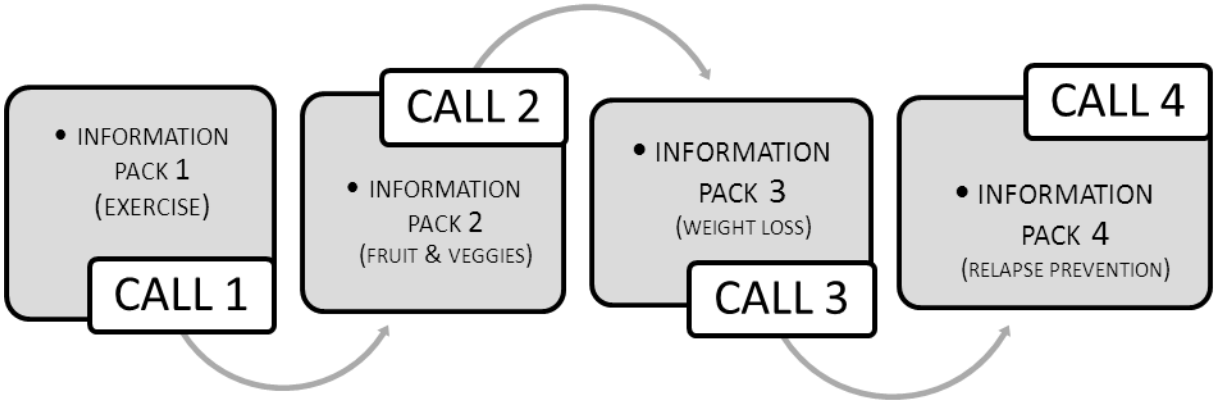
Thank you for your assistance in this part of the study, your participation is valuable and will help us with our research.

Yours sincerely

Dr Angela Craigie
Centre for Public Health Nutrition Research

Division of Clinical & Population Sciences & Education (CPSE)

Diagram illustration information and call scheduling for HEALTHFORCE 2.



Appendix O

Alere Cholestech LDX® System

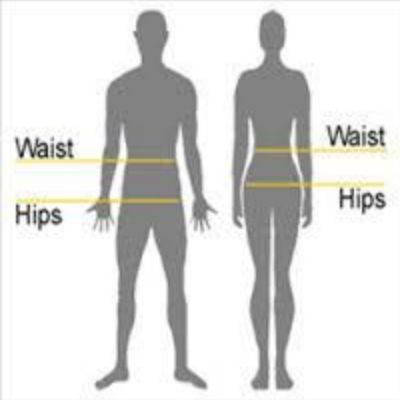
Multi Analyser Kit

Appendix O

eSecure - Aneroid Sphygmomanometer Blood Pressure Monitor Meter

Seca Leicester Stadiometer

Seca 703 Wireless 360 High Capacity Digital Medical Scale


Waist
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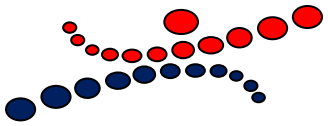
Appendix P



E-mail: a.craigie@dundee.ac.uk
Tel: 01382 496788

Date

RE: HEALTHFORCE 2 STUDY

Dear

We hope you found your first HEALTHFORCE 2 consultation useful, and have had some success in making some changes to your activity levels. As your next consultation is due shortly I am writing to provide you with your second information pack. We hope this will be useful in helping you to think about any improvements you could make to your diet and monitor your progress. Your lifestyle counsellor will refer to these during their telephone consultation so it would be useful if you could have these in front of you during the call.

If you have any questions relating your consultations you may contact your lifestyle counsellor on 01382 496788. Alternatively, if you have any questions about TASCFORCE or HEALTHFORCE 2 please contact Dr Roberta Littleford, our trial manager on 01382 633963.

Yours sincerely

E-mail: a.craigie@dundee.ac.uk
Tel: 01382 496788

Date

RE: HEALTHFORCE 2 STUDY

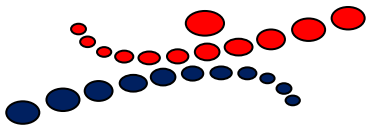
Dear

We hope you found your second HEALTHFORCE 2 consultation useful, and have been successful in making some changes to your diet and activity levels. As with my previous letter, I am writing to provide you with your next information pack. Your next consultation is scheduled to take place shortly and your lifestyle counsellor will refer to these during the telephone call. We hope the materials provided will helping you to keep you motivated to continue with the changes you have made so far, and to think about any further changes you could make to reduce your weight.

If you have any questions relating your consultations you may contact your lifestyle counsellor on 01382 496788. Alternatively, if you have any questions about TASCFORCE or HEALTHFORCE 2 overall please contact Dr Roberta Littleford, our trial manager on 01382 633963.

Yours sincerely

Dr Angela Craigie
Centre for Public Health Nutrition Research
Division of Clinical & Population Sciences & Education (CPSE)



E-mail: a.craigie@dundee.ac.uk
Tel: 01382 496788

Date

RE: HEALTHFORCE 2 STUDY

Dear

We hope you found your third HEALTHFORCE 2 consultation useful, and have managed to successfully lose some more weight by continuing with the changes to your diet and activity levels. We realise this isn't always easy, but your lifestyle counsellor is on hand to support you with this. Your next consultation is scheduled to take place shortly and I enclosed your last information pack. It would be useful if you could have these at hand during the consultation.

We hope the materials provided will help to you to keep you motivated to continue with the lifestyle changes you have made so far - not just over the next month, but also in the future. Remember, if you have any questions relating your consultations you may contact your lifestyle counsellor on 01382 496788.

Your final follow-up visit to Ninewells Hospital will be due around 4 weeks after this consultation. Before this consultation you will be contacted to confirm your appointment. You will also be posted 3 short questionnaires to complete before this appointment. In the meantime, if you have any questions about TASCFORCE or HEALTHFORCE 2 overall please contact Dr Roberta Littleford, our trial manager on 01382 633963.

Yours sincerely

Dr Angela Craigie
Centre for Public Health Nutrition Research
Division of Clinical & Population Sciences & Education (CPSE)

Appendix Q

		Telephone consultation 1 Stage 1	Telephone consultation 2 Stage 2	Telephone consultation 3 Stage 3	Telephone consultation 4 Stage 4
Study Characteristics	**Time plan**	**(Weeks 0-4)**	**(Weeks 4-8)**	**(Weeks 8-12)**	**(Weeks 12-16)**
	Focus	**Physical Activity (PA)**	**Fruit and Vegetable (F&V) & PA**	**Weight loss, PA, F&V**	**Relapse prevention, PA, F&V**
	Aim	**Minimum increase of at least 30 minutes per week (towards achieving current target for moderate exercise of 30 mins on most days of the week)**			
			Minimum increase of at least 1 portion per day (towards achieving current target of 5 portions of fruit and vegetables per day)		
				Weight loss of -7% from baseline	
					Avoidance of weight regain
	Contact				
	Face to Face	One to one telephone counselling	One to one telephone counselling	One to one telephone counselling	One to one telephone counselling
	Plus Multiple Contacts	Optional telephone support	Optional telephone support	Optional telephone support	Optional telephone support
	Counselling Session Duration	30 minutes	30 minutes	30 minutes	30 minutes
	Who Delivers	Trained staff as appropriate	Trained staff as appropriate	Trained staff as appropriate	Trained staff as appropriate
	Content				
	Motivational Approaches a) Goal Setting b) Tools / gift	- Personalised PA goal 1 - Pedometer	- Personalised F&V intake goal and PA goal 2 - Apple corer / vegetable steamer	- Personalised body shape/weight maintenance goal, PA goal 3 and re-emphasis of F&V goal - Tape measure	- Personalised body shape/weight loss goal with limits for weight regain, PA goal 4 and re-emphasis of F&V goal - Energy content of Alcohol wheel
	Behavioural Approaches	- Walking Record - Feedback at Telephone call 2	- 5 a day food diary - Feedback at Telephone call 3	- Weight log book - Feedback at Telephone call 4	- 'Ten top tips' progress chart - Feedback at follow-up visit
	Educational Approaches	- Images of impact of weight gain/loss on CVD risk - PA literature	- F&V literature (including recipes)	- Healthy weight literature e.g. portion control, snacking	- Ten top tips for a healthy weight leaflet
	± Suggested group activities (as available from existing community groups)	Physical activity groups e.g. walking, keep fit, badminton	Healthy eating groups e.g. cooking skills	Weight reduction groups	Weight reduction groups
	Psycho-social Aspects				
	Behaviour theory	Emphasis on self efficacy ± stages of change	Emphasis on self efficacy ± stages of change	Emphasis on self efficacy ± stages of change	Emphasis on relapse prevention
	Social Support	Encourage enlisted support of friend / partner	Encourage enlisted support of friend / partner	Encourage enlisted support of friend / partner	Encourage enlisted support of friend / partner
	Personalisation	- Involve decisional balance - Encourage small changes - Discuss "cheap & easy" options and "investment" priorities	- Involve decisional balance - Encourage small changes - Discuss "cheap & easy" options and "investment" priorities	- Involve decisional balance - Encourage small changes - Discuss "cheap & easy" options and "investment" priorities	- Involve decisional balance - Encourage small changes - Discuss "cheap & easy" options and "investment" priorities

Appendix R

Sensitivity Analysis

A sensitivity analysis was carried out on the primary outcome data to assess robustness and consider what impact certain influences may have on the primary outcome data such as missing data and outliers. The analysis intended to show the level of consistency between the results of the primary analysis and the results from the sensitivity analysis to strengthen the conclusions and credibility of the findings. The sensitivity analysis would control for the effect of missing data, outliers and the impact of distributional assumptions on the primary outcome weight loss.

Missing data

As the study was powered to a detect weight loss of 7%, intention to treat analyses were carried out on the primary outcome only and secondary outcomes analysis carried out only on subjects who completed the study. To preserve sample size and prevent bias from a non-representative sample a multiple imputation method was used. Selecting a random number generator program in SPSS allowed missing values to be replaced giving reasonable assurance that the values that were replaced through the process were appropriate and matched the data that was missing. This method gave a best estimate of what the actual missing values were likely to have been.

Process of Imputing missing values

The process was carried out in SPSS version 21. Multiple simulations were run relative to the available data in order to identify the probability value of the missing data and create a full

data set. Several iterations were run to find the best fit to replace the missing data. A pattern of analysis test run first to identify if the missing data was random or systematic indicated that the results showed a non monotonisity, i.e. no pattern. Thus, it was concluded that the data was randomly missing. This confirmed there was minimal risk of the original data being biased by missing data. Numbers were then selected from the random number generator program Mersenne Twister and five simulations were chosen. Each of the 5 simulations generated a value for the variables used as predictors for imputing the missing values. The final value selected to replace the missing value was an average of the 5 simulations. The full data set was then used to compare results from the original primary analysis with the imputed missing data.

Test for normality

Visual interpretation of the data in the form of histograms, box plots and QQ plots were explored to test for normality of data distribution on the primary outcome variable (kg weight loss). The result showed a right skewed distribution with kurtosis displaying a leptokurtic distribution, (where the distribution of data is more peaked than that of a normal or 'bellcurve' distribution) a skewness of 2.38 (SE 0.14) and kurtosis of 22.95 (SE 0.28). Both Kolmogorov-Smirnov and Shapiro-Wilk tests also confirmed a p value of <0.05, thereby rejecting the null hypothesis and concluding that the sample did not follow a normal distribution. There was little difference in the mean weight loss in the original data (n = 246), 1.63kg (SD 3.82) compared with the mean of the imputed data (n= 314), 1.49kg (SD 3.94) (Figures 5.1 and 5.2)

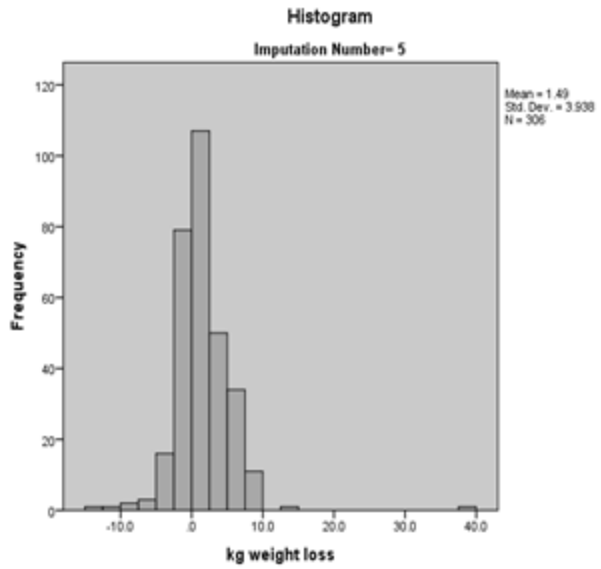


Figure **Error! No text of specified style in document.**.2: kg weight loss with imputed data

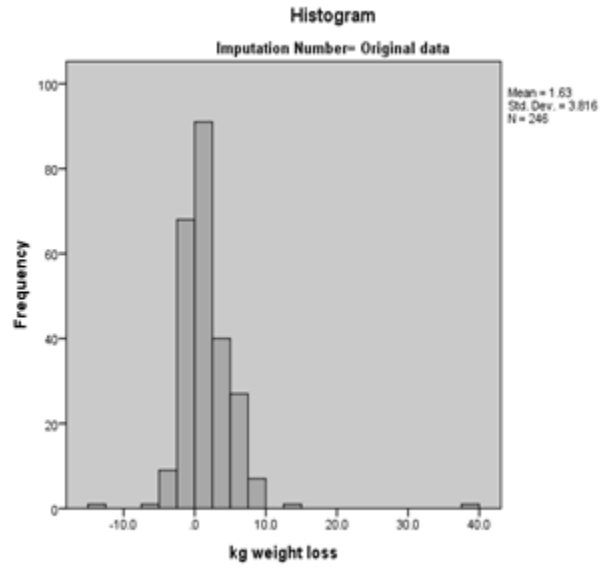


Figure **Error! No text of specified style in document.**.3: kg weight loss original Data

Minimising the effect of outliers

As the data followed a positive skew for kg weight loss the next step was to carry out a log transformation in an attempt to normalise the data. The result showed a mean weight loss of 0.32kg (SE 0.33) for the original data and skewness of -0.48 (SE 0.19) and kurtosis of 0.58 (SE 0.38), and in the imputed data a mean of 0.33kg (SE 0.30), a skewness of -0.67 (SE 0.17) and kurtosis of 0.76 (SE 0.34). The Kolmogorov-Smirnov test confirmed a p value of <0.05 for the original data. The Kolmogorov-Smirnov and Shapiro-Wilk tests rejected the null hypotheses for normality for imputed data concluding that log transforming the data did not produce a normal distribution. Figure 5.3 shows QQ plot with Log_{10} transformation.

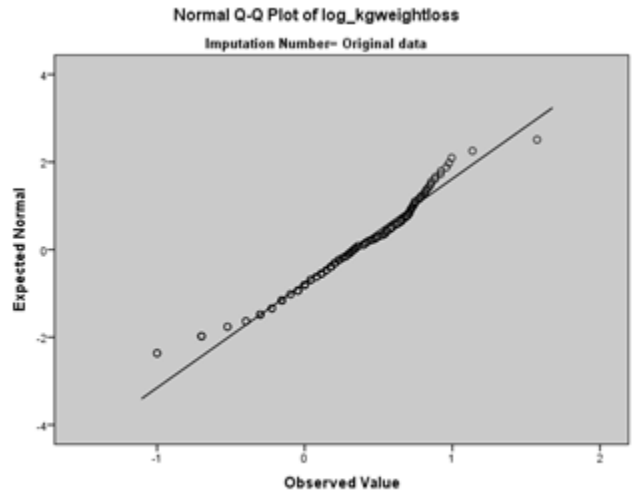


Figure **Error! No text of specified style in document.**.4: QQ Plot kg weight loss Log_{10} Transformed Original Data

A second attempt to normalise the data distribution computed Z-scores to identify outliers.

Scores greater than 3 and less than -3 were considered outliers and removed, the results showed a mean kg weight loss of 1.24kg (SE 0.72 skewness of -0.07 (SE 0.06) and kurtosis of 0.50 (SE 0.12), with the skew now changing to a negative skew but with more normal kurtoses. Figure 5.4 shows the original kg weight loss data without conversion of outliers whilst figure 5.5 shows QQ plot of kg weight loss with converted z scores on original data.

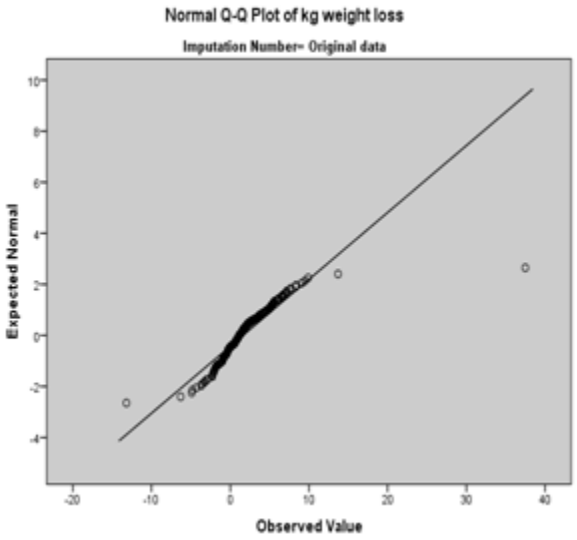


Figure **Error! No text of specified style in document.**.5: QQ Plot kg weight loss original data

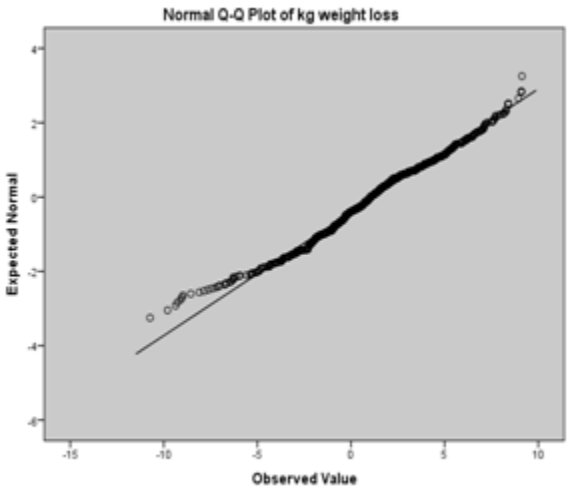


Figure **Error! No text of specified style in document.**.6*:* QQ Plot kg weight loss outliers removed with z scores (original data)

Appendix S

Two-variable model to predict weight loss

Predictor Variables	P -values	All Variables significant	Adjusted R^2
Randomised Group Seasonal Group	<0.001 0.005	Yes	0.065
Randomised Group Marital Status	<0.001 <0.005	Yes	0.088
Randomised Group Employment Status	<0.001 0.015	Yes	0.088
Randomised Group BMI kg/m^2	<0.001 0.871	No	0.014
Randomised Group Hip/Waist Ratio	<0.001 0.416	No	0.078
Randomised Group Educational Attainment	<0.001 0.503	No	0.083
Randomised Group Baseline Total Cholesterol	<0.001 0.789	No	0.033
Randomised Group SIMD	<0.001 0.332	No	0.069
Randomised Group Gender	<0.001 0.116	No	0.074
Seasonal Group Marital Status	0.031 0.003	Yes	0.088
Seasonal Group Gender	0.031 0.309	No	0.044
Seasonal Group BMI kg/m^2	0.031 0.837	No	0.031
Seasonal Group Hip/Waist Ratio	0.031 0.490	No	0.043
Seasonal Group Educational Attainment	0.004 0.773	No	0.040
Seasonal Group Baseline Total Cholesterol	0.004 0.619	No	0.028
Seasonal Group SIMD	0.003 0.234	No	0.047
Seasonal Group Employment	0.004 <0.001	Yes	0.013
Employment Status	<0.001	No	0.017

Gender	0.225		
Employment Status BMI kg/m^2	<0.001 0.887	No	0.055
Employment Status Hip/Waist Ratio	<0.001 0.387	No	0.026
Employment Status Marital Status	<0.001 0.009	Yes	0.013
Employment Status Educational Attainment	<0.001 0.973	No	0.013
Employment Status Baseline Total Cholesterol	<0.001 0.834	No	0.019
Employment Status SIMD	<0.001 0.649	No	0.014
Marital Status Gender	<0.005 0.411	No	0.063
Marital Status BMI kg/m^2	<0.005 0.761	No	0.011
Marital Status Educational Attainment	<0.005 0.878	No	0.054
Marital Status Baseline Total Cholesterol	<0.001 0.554	No	0.056
Marital Status SIMD	<0.001 0.469	No	0.062
Marital Status Hip/Waist Ratio	0.009 0.492	No	0.064

Three variable model to predict weight loss

Predictor Variables	P -values	All Variables significant	Adjusted R^2
Randomised Group Seasonal Group Marital status	<0.001 0.034 0.009	Yes	0.085
Randomised Group Seasonal Group Employment	<0.001 0.007 <0.001	Yes	0.085
Randomised Group Seasonal Group BMI kg/m^2	0.002 0.021 0.840	No	0.036
Randomised Group Seasonal Group Hip/Waist Ratio	<0.005 0.096 0.560	No	0.077
Randomised Group Seasonal Group Educational Attainment	<0.001 0.033 0.593	No	0.084
Randomised Group Seasonal Group Baseline Total Cholesterol	<0.001 0.005 0.702	No	0.083
Randomised Group Seasonal Group SIMD	<0.001 0.004 0.224	No	0.062
Randomised Group Seasonal Group Gender	<0.001 0.007 0.152	No	0.073
Seasonal Group Employment Status Marital Status	<0.001 0.012 0.026	Yes	0.009
Seasonal Group Employment Status Gender	0.005 <0.001 0.329	No	0.014
Seasonal Group Employment Status BMI kg/m^2	0.031 <0.001 0.880	No	0.010
Seasonal Group Employment Status Hip/Waist Ratio	0.022 <0.001 0.406	No	0.023
Seasonal Group	0.004	No	0.009

Employment Status Education	<0.001 0.977		
Seasonal Group Employment Status Baseline Total Cholesterol	0.004 <0.001 0.736	No	0.015
Seasonal Group Employment Status SIMD	0.003 <0.001 0.338	No	0.010
Marital Status Employment Status Gender	0.010 <0.001 0.331	No	0.013
Marital Status Employment Status BMI kg/m^2	0.005 <0.005 0.778	No	0.011
Marital Status Employment Status Hip/Waist Ratio	0.022 <0.001 0.375	No	0.023
Marital Status Employment Status Educational Attainment	0.012 <0.001 0.991	No	0.009
Marital Status Employment Status Baseline Total Cholesterol	0.002 <0.001 0.633	No	0.015
Marital Status Employment Status SIMD	0.009 <0.001 0.656	No	0.010

Four variable Modelling

Predictor Variables	P -values	All Variables significant	Adjusted R^2
Randomised Group Seasonal Group Employment Status Marital Status	0.087 <0.001 0.015 <0.001	No	0.081
Randomised Group Seasonal Group Employment Attainment Gender	<0.001 0.008 <0.001 0.157	No	0.091
Randomised Group Seasonal Group Employment Status BMI kg/m^2	<0.005 0.096 <0.001 0.864	No	0.086
Randomised Group Seasonal Group Employment Status Hip/Waist Ratio	<0.001 0.055 <0.001 0.409	No	0.094
Randomised Group Seasonal Group Employment Status Marital Status	<0.001 0.015 <0.001 0.087	No	0.081
Randomised Group Seasonal Group Employment Status Educational Attainment	<0.001 0.028 <0.001 0.907	No	0.091
Randomised Group Seasonal Group Employment Status Baseline Total Cholesterol	<0.001 0.005 <0.001 0.744	No	0.088
Randomised Group Seasonal Group Employment Status SIMD	<0.001 0.005 <0.001 0.414	No	0.081
Marital Status Randomised Group Seasonal Group Gender	0.012 <0.001 0.035 0.231	No	0.091
Marital Status	0.006	No	0.086

Randomised Group Seasonal Group BMI kg/m^2	0.009 0.047 0.702		
Marital Status Randomised Group Seasonal Group Waist	0.052 0.004 0.192 0.613	No	0.095
Marital Status Randomised Group Seasonal Group Educational Attainment	0.022 <0.001 0.127 0.887	No	0.085
Marital Status Randomised Group Seasonal Group Baseline Total Cholesterol	0.008 0.003 0.025 0.609	No	0.088
Marital Status Randomised Group Seasonal Group SIMD	0.012 <0.001 0.027 0.300	No	0.081